

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

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U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Biotechnology Regulatory Services

Public Stakeholder Meeting

USDA Center at Riverside

4700 River Road

Riverdale, Maryland 20737

December 1, 2010

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

2

1 A G E N D A

2 Welcome Clint Nesbitt, Moderator PAGE 4
3 Chief of Staff
4 Biotechnology Regulatory Services

5 MORNING SESSION

6 APHIS Update 13
7 Michael Gregoire, Deputy Administrator
8 Biotechnology Regulatory Services
9 National Environmental Policy Act 33
10 John Turner, Division Director
11 Environmental Risk Analysis Program
12 BRS NEPA Process 38
13 Craig Roseland, NEPA Team
14 Environmental Protection Specialist
15 BRS NEPA Pilot Project 61
16 Rebecca Stankiewicz Gabel
17 Senior Environmental Protection
18 Specialist
19 BRS Outreach Programs 76
20 Tracy Bowman, Director
21 Policy Coordination Program
22 Group Discussions 89
Feedback on APHIS Web site

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

3

1	AFTERNOON SESSION	
2	Clint Nesbitt, Moderator	111
3	Overview of the Freedom of Information Act	111
4	Anastazia Taylor, Project Manager Freedom of Information Act Office	
5		
6	Update and Changes to ePermits	146
7		
8	Lee Handley, Senior Biotechnologist Risk Assessment Branch	
9		
10	Update on Biotechnology Quality Management System	159
11	Tom Sim, Division Director Regulatory Operations Program	
12		
13	Question and Answer Session	166
14		
15		
16		
17		
18		
19		
20		
21		
22		

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

4

1 P R O C E E D I N G S

2 MR. CLINT NESBITT: So I'd like to
3 welcome everyone this morning to the APHIS/BRS
4 Stakeholders' Meeting. My name is Clint Nesbitt. I'm
5 the Chief of Staff with APHIS/BRS, and I'm going to be
6 acting as the MC for the events today, but primarily
7 that means that I'll be the timekeeper, so my job is
8 make sure as best as possible we stay on schedule.

9 I'm going to begin with just a couple of
10 logistically announcements before I turn the floor
11 to Mike Gregoire. If you have not signed up for lunch
12 yet, please do so as soon as possible because I think
13 by 11:00 at the latest we'll place orders. See, I
14 think, Helena or Gail in the front. Lunches are \$10.
15 If you don't want to order lunch ahead of time, we do
16 have a cafeteria here in the building. We have water
17 at the back of the room, but there is Dunkin Donuts
18 coffee and donuts apparently in the cafeteria, so
19 you're welcome to use that opportunity for breaks.

20 In order to keep things on time as we go
21 through the presentation, I may sort off close off
22 of the conversations a little bit quickly to keep on

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Biotechnology Regulatory Services Meeting 12-01-2010

5

1 schedule, but we do have some time at the end of the
2 day for questions and discussion. So what I may do as
3 we move along, if we are in the midst of a discussion
4 and need to continue to discussing things more, I may
5 sort of put thing into a parking lot, and we'll come
6 back to certain issues at the end of the day if we
7 to discuss things further.

8 I would also like to mention that we do a
9 court reporter. He's over here at the side: Jeffrey.
10 Hello, Jeffrey. So because we have a court reporter,
11 keep in mind that everything that we're saying here is
12 being transcribed and will be published on the Web
13 probably in about two weeks. So because of that, we
14 need to make sure that everyone is speaking into a
15 microphone at some point. I have some hand-helds here
16 that I'll be passing around when we have discussion
17 from the floor, but when I do hand you a mic, please
18 remember to state your name and your organization so
19 we'll know who it is that's speaking.

20 There will be, I think, at least one
21 opportunity where we'll have discussions at tables in
22 table groups. For those discussions, obviously, we

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Biotechnology Regulatory Services Meeting 12-01-2010

6

1 can't transcribe that, but we will be kind of
2 the discussion on flipcharts, and we will have
3 on the record afterward.

4 Let's see. Anything else? I think that's
5 the main points for now. I may make some more
6 announcements later, but before I turn the microphone
7 over to Mike for his introductory remarks, I would
8 to ask the folks in the room to introduce themselves,
9 and I think I should do this by passing around a
10 microphone.

11 (Pause)

12 MR. MICHAEL GREGOIRE: I'm Mike Gregoire,
13 Deputy Administrator for BRS and APHIS.

14 MR. J. R. STANDER: J. R. Stander of
15 Betaseed.

16 MR. JAY MILLER: Jay Miller of
17 Betaseed.

18 MS. NATALIE WEBER: Natalie Weber
19 with DuPont.

20 MR. STEPHEN CLAPP: Steve Clapp,
21 Chemical News.

22 MR. DAVE REINHOLD: Dave Reinhold of

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Biotechnology Regulatory Services Meeting 12-01-2010

7

1 BRS.

2 MS. ANNIE GUTSCHE: Ann Gutsche of
3 DuPont.

4 MS. LINDA NYGAARD: Linda Nygaard
5 with Dow AgroSciences.

6 MS. AMBER STEPHON: Amber Stephon,
7 Dow AgroSciences.

8 MR. RAY DOVER: Ray Dover of Monsanto.

9 MS. LISA BAKER: Lisa Baker with Dow
10 AgroSciences.

11 MR. GREGORY ORR: Greg Orr, Dow
12 AgroSciences

13 MR. JOHN TURNER: John Turner
14 APHIS/BRS.

15 MS. PAULA BODEY: Paula Bodey, The
16 Scotts Company.

17 MS. BEVERLY SIMMONS: Beverly
18 Simmons. I'm the Associate Deputy Administrator at
19 BRS.

20 MS. ISABELLE COATS: Isabelle Coats,
21 CropScience.

22 MS. GINA BEUHNER: Gina Beuhner, Dow

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Biotechnology Regulatory Services Meeting 12-01-2010

8

1 AgroSciences.

2 MR. DAVE HERON: Good morning. Dave

3 Heron

4 APHIS/BRS.

5 MR. DAVID WHALEN: David Whalen,

6 Forage Genetics.

7 MR. SINOR RENNET: Sinor Rennet (ph)

8 Forage Genetics.

9 MS. SHARIE FITZPATRICK: Sharie

10 Fitzpatrick, Metabolix.

11 MS. DAWN GILL: Dawn Gill, Dow

12 AgroSciences.

13 MR. ROBERT ROSADO: Rob Rosado, Bio.

14 MR. TODD DOHRMANN: Todd Dohrmann,

15 Monsanto.

16 MR. TODD STALEY: Todd Staley,

17 Monsanto.

18 MS. MARIA DESAGUN: Maria Desagun,

19 Ceres, Incorporated.

20 MR. DAN JENKINS: Dan Jenkins,

21 Monsanto.

22 MR. STEVE METGIN: Steve Metgin (ph),

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Biotechnology Regulatory Services Meeting 12-01-2010

9

1 National Cotton Council.

2 MR. RICHARD GEORGE: Dick George with BRS
3 starting next week.

4 (Laughter)

5 MR. EDWARD RUCKERT: Ed Ruckert,
6 McDermott, Will & Emery.

7 MS. SHARON CANNISTRA: Sharon
8 Cannistra, Center for Science in the Public Interest.

9 MS. TRACY BOWMAN: Tracy Bowman, BRS.

10 MR. GREGORY PARHAM: Gregory Parham,
11 Associate Administrator APHIS.

12 (Pause)

13 MR. JACK OKAMURO: Jack Okamuro,
14 Research Services, USDA.

15 MR. JUSTIN MEYERS: Justin Meyers,
16 Nelson Mullins.

17 MR. RAUL GIDDENS: Raul (ph) Giddens,
18 independent consultant.

19 MR. GREGORY WITUCKI: Greg Witucki,
20 Syngenta.

21 MR. JEFFERY BOTTOMS: Jeff Bottoms,
22 Syngenta.

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Biotechnology Regulatory Services Meeting 12-01-2010

10

1 MR. MICHAEL HALL: Mike Hall, Monsanto.
2 MR. LARRY ZEPH: Larry Zeph, Syngenta
3 MR. MICK SORA: Mick Sora (ph), Dow
4 AgroSciences.
5 MS. JILL ACHOR: Jill Achor, Dow
6 AgroSciences.
7 MS. NICOLE JUBA: Nicole Juba,
8 Virginia Tech.
9 MR. GLEN ROGAN: Glen Rogan, I'm with
10 Monsanto Company.
11 MR. NESBITT: And we have APHIS staff
12 in the back. Andre.
13 MR. ANDRE BELL: Andre Bell, BRS.
14 MR. SURAJ GUPTA: Suraj Gupta with
15 BRS.
16 MS. SABRINA FERGUSON: Sabrina Ferguson,
17 BRS.
18 MS. KAREN WALKER: Karen Walker, BRS.
19 MR. WILLIAM DOLEY: Bill Doley with
20 BRS.
21 MR. SU BAN: Su Ban (ph), BRS.
22 MS. MARGRET JONES: Margaret Jones,

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Biotechnology Regulatory Services Meeting 12-01-2010

11

1 BRS.
2 MS. SALLY MCCAMMON: Sally McCammon with
3 BRS.
4 MR. GREGORY HOOKER: Greg Hooker, BRS.
5 MS. RACHEL IADICICCO: Rachel Iadicicco,
6 Office of Program and Development.
7 MS. TERRI DUNAHAY: Terri Dunahay,
8 BRS.
9 MR. ANABOL CACEB: Anabol Caceb (ph),
10 BRS.
11 MR. CARLOS BLANCO: Carlos Blanco,
12 BRS.
13 MR. HAROLD WISE: Harold Wise, BRS.
14 MS. AKELA GIBSON: Akela (ph) Gibson,
15 MR. MICHAEL MENDELSON: Mike
16 Mendelson, Environmental Protection Agency.
17 MS. KAREN RAIN: Karen Rain (ph), BRS.
18 MS. NICOLE RUSSO: Nicole Russo, BRS.
19 MR. JORDAN SOTTOSANTO: Jordan
20 BRS.
21 MS. GWEN BURNETT: Gwen Burnett, BRS.
22 MS. KAREN RATZOW: Karen Ratzow,

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Biotechnology Regulatory Services Meeting 12-01-2010

12

1 Policy and Program Development.

2 MS. PAULINE SPAINE: Pauline Spaine, BRS.

3 MS. LINDA BARDOT: Linda Bardot, BRS.

4 MR. LEE HANDLEY: Lee Handley, BRS.

5 MS. DAWN MALLOY: Dawn Malloy, BRS.

6 MS. TESSA HUFF: Good morning.

7 Huff (ph), BRS.

8 MR. STEPHEN BENNETT: Steve Bennett

9 with BRS.

10 MS. ANN DEHUBERT: Ann Dehubert (ph),

11 MS. COLLEEN WOOD: Colleen Wood, BRS.

12 MR. NESBITT: Well, (inaudible).

13 (Laughter)

14 MR. SID ABEL: Sid Abel, BRS.

15 MR. JOHN CORDTS: John Cordts, BRS.

16 MR. NESBITT: Okay. Did I miss anyone?

17 Oh, (inaudible).

18 MR. DAVID LEE: David Lee, Edenspace.

19 FEMALE SPEAKER: (inaudible).

20 MR. NESBITT: Okay. We got Rebecca in

21 back. Okay. Last two.

22 MR. CRAIG ROSELAND: I'm Craig Roseland,

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Biotechnology Regulatory Services Meeting 12-01-2010

13

1 BRS.

2 MS. REBECCA STANKIEWICZ GABEL: I'm

3 Rebecca Stankiewicz Gabel with BRS.

4 MR. NESBITT: Okay. I think we've got
5 everybody now, so I will turn the podium over to Mike
6 Gregoire.

7 MR. GREGOIRE: Okay. Thank you,
8 Clint. Can you hear me okay in the back? No. Gwen's
9 waving at me. What does that mean?

10 MS. BURNETT: I can't hear you in the
11 back.

12 MR. GREGOIRE: Okay.

13 (Pause)

14 MR. GREGOIRE: Is that better?

15 (Pause)

16 MR. GREGOIRE: Okay. Good morning,
17 everybody, and welcome to our annual BRS Stakeholder
18 meeting. I very much appreciate everyone coming out
19 today especially with the weather being as it is
20 I was surprised to see as many people as we did so
21 early this morning. I myself left really, really
22 today just to make sure I wasn't late for this.

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Biotechnology Regulatory Services Meeting 12-01-2010

14

1 The theme of our meeting today is Focus on
2 Transparency, and one of the first Executive Orders
3 that

4 President Obama issued dealt with open
5 government and transparency. And in that Executive
6 Order, he said three things: One, that government
7 should be transparent; government should be
8 participatory; and government should be collaborative.
9 So it's in the spirit of that Executive Order that
10 we're holding our meeting today, and the purpose of
11 meeting is to share with you information about some of
12 our accomplishments from last year, our priorities for
13 this year, some of the new initiatives that we're
14 dealing with to provide you with information on those,
15 to answer questions you may have about those, and to
16 get your input, ideas, and suggestions around the
17 different areas that we're going to be talking about
18 today.

19 Let me just begin by reviewing today's
20 agenda. It should be in the packet that is on your
21 table there. I'm just going to walk through that
22 briefly.

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Biotechnology Regulatory Services Meeting 12-01-2010

15

1 To begin the meeting, I'll be making some
2 remarks about what our priority focus areas are, key
3 accomplishments from 2010, our priorities for 2011,
4 discuss some other current issues that I think are of
5 interest to people. We had 45 minutes set out for the
6 first part of the agenda here. I will take questions
7 after I make my remarks, and if we run out of time for
8 me to answer those questions, we do have time set
9 at the end of the day to continue that discussion and
10 for us to answer your questions.

11 I think we will also during the course of
12 day if there are questions that come up that the
13 presenter aren't prepared to respond to we're going to
14 keep kind of a running list of those questions that
15 come up during the course of the day, and we'll make
16 every effort to respond to those at the session at the
17 end of the day.

18 So after we complete the first part, this
19 morning session, we will focus on two areas. The
20 deals with the implementation of the National
21 Environmental Policy Act within BRS/APHIS, how we
22 complete our NEPA analysis and talk about a NEPA pilot

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Biotechnology Regulatory Services Meeting 12-01-2010

16

1 project that we're going to be rolling out shortly.

2 We will then be talking about our Web site.

3 We want to have a discussion about that. We had

4 feedback in previous meeting that we have

5 to improve the Web site to make it easier to navigate

6 and to provide the content that people are looking

7 so this is an area we would really appreciate your

8 input and suggestions because that is something that

9 want to improve and make more useful to stakeholders.

10 We'll be breaking for lunch it look like 12:15 for an

11 hour and a half, and Clint mentioned you can order

12 lunch up at the table there.

13 This afternoon, we're going to talk about

14 FOIA process, and then we'll provide updates on

15 ePermits in the Biotechnology Quality Management

16 System. And again, we'll take questions and answers

17 and do a wrap-up for the day. So that's what we have

18 planned today.

19 With that, let me turn to my remarks about

20 the state of BRS. I want to begin by saying that I

21 think our work is really important. It's exciting,

22 it's challenging. I heard -- I was listening to the

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Biotechnology Regulatory Services Meeting 12-01-2010

17

1 radio last night on the way home from work, and they
2 were interviewing a British researcher on the radio
3 had done a very thorough study and determined that
4 April 11, 1954, was the most boring in modern history.

5 (Laughter)

6 MR. GREGOIRE: And he came to this
7 conclusion by just examining the news events of the
8 day, and he concluded that April 11, 1954, in his own
9 words was spectacularly uneventful.

10 (Laughter)

11 MR. GREGOIRE: And some day, I would
12 long for April 11, 1954.

13 (Laughter)

14 MR. GREGOIRE: So with that, I want
15 to say that we are really focused on strengthening the
16 biotechnology regulatory program and building the
17 capacity of our program to handle the growing volume
18 and complexity of the work that is before us.

19 Programmatically, our priorities are to
20 strengthen the compliance program to improve the crop
21 deregulation regulation process and to continue to
22 ensure the safe introduction and release of

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Biotechnology Regulatory Services Meeting 12-01-2010

18

1 engineered organisms.

2 One of the things I wanted to bring you up
3 date on is some organizational changes that we have
4 made since our last meeting last year that I think
5 the program in a better position long term to, again,
6 deal with the growing workload and increasingly
7 workload that we've had. So we've made a number or
8 organizational changes, and we have a number of new
9 employees in BRS that have been brought onboard or
10 changed positions in BRS since we met last year, and
11 I'll introduce some of those people, but I would
12 encourage you during the breaks and so on to introduce
13 yourselves to our staff, a lot of whom are in the back
14 of the room today.

15 First of all, we have four divisions in
16 Biotechnology Regulatory Services. One of those
17 divisions is called Environmental Risk Analysis
18 Programs. The most important change that we've made in
19 that staff was to create a separate NEPA, and this is
20 staff that is devoted to developing or overseeing the
21 development of the NEPA documents that inform our
22 regulatory decisions. Prior to have a separate NEPA

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Biotechnology Regulatory Services Meeting 12-01-2010

19

1 team. That work was embedded in that staff, but we
2 didn't have a standalone team, so an important change
3 that we've made is to create that team that now has
4 three members, and that team is going to grow this
5 year. I think you're going to hear a little bit more
6 about it in this morning's presentation when we're
7 talking about NEPA issues.

8 In the Regulatory Operations Program, this
9 the compliance side of work. We've created a new
10 compliance assistance branch, and the staff we had in
11 the regions we created regional compliance assurance
12 branches. Prior to that, we had a lot of these
13 function lumped together. We had one supervisor that
14 had a very, very wide span of control, so we've
15 some new branches to have a more reasonable span of
16 control within the Regulatory Operations Program to
17 create this new compliance assistance branch.

18 In the Policy Coordination Programs, we
19 into two branches what was combined in one previously,
20 so we will now have a Government Relations branch that
21 will handle all of our international activities as
22 as state and tribal relations that the program has.

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Biotechnology Regulatory Services Meeting 12-01-2010

20

1 Then we'll have a separate communications branch, and
2 we will continue to have Regulatory and Environmental
3 Analysis branch, but we are bringing more policy
4 analysts into that staff to strengthen our policy
5 analysis capability. So those are some of the key
6 organizational changes.

7 We have also over the last year contracted
8 for additional assistance to supplement our in-house
9 resources, so we're getting contract assistance, for
10 example, to help evaluate public comments that we get
11 on dockets that we publish as well as to help prepare
12 the NEPA documents that inform our regulatory
13 decisions.

14 Let me just put some names to some of those
15 organizational entities that I talked about. I've
16 in BRS not quite three years and sort of getting to
17 point now of where I'm one of the old-timers. Since
18 the last meeting about a year ago, we've hired 18 new
19 employees in BRS, so almost one-quarter of our total
20 number of employees are new to BRS. At the division
21 director level, by early next year, we will basically
22 have a whole new team in place. John Turner, who the

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Biotechnology Regulatory Services Meeting 12-01-2010

21

1 head of policy coordination programs, has moved over
2 and is now the director of the Environmental Risk
3 Analysis Program.

4 Tracy Bowman is the new director of the
5 Policy Coordination Program. Tracy, raise your hand.
6 Tracy is someone that I've worked with a long time,
7 comes to us in BRS from Policy and Program Development
8 in APHIS and has very extensive and great experience
9 policy analysis kinds of issues.

10 Sabrina Ferguson -- Sabrina, raise your hand
11 -- is the new director of our resources management
12 programs in BRS. Sabrina's staff handles the budget
13 and personnel and procurement, property management and
14 IT issues for the organization.

15 And then Tom Sim. Where is Tom? I don't
16 Tom. Tom, who I think many of you know, is retiring
17 the end of this year. I think his last day in the
18 office is next Friday, so, hopefully, Tom -- well, Tom
19 will be here for a part of the session today. Tom
20 insisted that we have this meeting before he retires
21 so -- (Laughter)

22 MR. GREGOIRE: -- and we just felt

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Biotechnology Regulatory Services Meeting 12-01-2010

22

1 was the right thing to do to accommodate Tom's wishes.
2 Again, I encourage you to introduce yourselves to our
3 staff members during the break and at lunchtime.

4 Our organizational chart is on our Web site.
5 If you're really interested in the nuts and bolts of
6 that, you can look at it on the Web site, and we'd be
7 happy to answer your questions about that or clarify
8 who does what and who to contact for what issues and
9 on.

10 Let me talk a little bit about last year,
11 last fiscal year, 2010, again, around the themes of
12 strengthening the compliance program, improving the
13 crop deregulation process, ensuring the safe
14 introduction and release of GE organisms and improving
15 transparency.

16 First of all with respect to improving
17 clients, we were very pleased to be able to implement
18 the Biotechnology Quality Management System last year.
19 Our goal was to enroll five additional entities in
20 program, which we did the last week of September, so
21 now have 10 entities enrolled in the program.

22 Our goal was also to publish a final BQMS

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Biotechnology Regulatory Services Meeting 12-01-2010

23

1 audit standard in the Federal Register by the end of
2 the fiscal year. We almost did that. It was October
3 when it was officially published, but I consider that
4 to be close enough to the end of the year to count
5 toward 2010.

6 As I said, we established a new compliance
7 assistance branch and regulatory operations programs,
8 and Dr. Ed Jhee is head of that branch and is leading
9 the BQMS implementation.

10 We also last year closed six open OIG audit
11 recommendations that had not been closed, so that
12 leaves us with 24 of 27 OIG audit recommendations that
13 have now been officially closed; that is, they have
14 been implemented to the satisfaction of the Office of
15 Chief Financial Officer in USDA. The three that
16 open are all related to new regulations. So that has
17 been a priority not just for BRS this past year but
18 all of APHIS; that is, to close any open OIG audit
19 recommendations, so we made good progress on that.

20 In terms of the petition process, I
21 we've been working on building the infrastructure of
22 the organization to be able to deal with the growing

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Biotechnology Regulatory Services Meeting 12-01-2010

24

1 number and complexity of those additions. We've hired
2 additional staff. We've implemented this NEPA team.
3 We've going to be talking about a NEPA pilot this
4 morning. We're contracting out additional work,
5 evaluating public comment, and preparing NEPA
6 documents.

7 We have sought additional appropriations
8 through the budget process for fiscal 2011 that would
9 increase the overall funding for this program from \$13
10 to about \$19 million. Most of that additional funding
11 will be devoted to resources on the petition process.

12 We are under a continuing resolution that
13 will fund us through Friday. I'm not sure what's
14 to happen after Friday. We'll likely be extended for
15 short period of time, so there remains a good deal of
16 uncertainty around the budget for this year. Prior to
17 their fall recess, they had made some progress on the
18 agricultural appropriations bill. The Senate
19 Appropriation Committee and their marked up of the
20 provided the full increase that was requested for this
21 program. The House full Committee on Appropriations
22 has not acted as yet that I'm aware of on this, so

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Biotechnology Regulatory Services Meeting 12-01-2010

25

1 that's something we're following very, very closely
2 will have an impact on what we have to work with this
3 year.

4 So having said that with respect to the
5 strengthening the infrastructure to deal with
6 petitions, when all is said and done what really
7 is how many of these we're able to get out. And quite
8 frankly, those results aren't what they should be, and
9 we're going to redouble our efforts in 2011 to
10 to focus on that process and improvements that we can
11 make.

12 With respect to safe introduction and
13 release of GE organisms, we again this past year
14 more than I think 2,068 notifications and permits. We
15 initiated more than 500 inspections. Our permit
16 process received ISO's newest quality management
17 standard, which we're very proud of, and we had no
18 significant LOP incidents in
19 2010.

20 For 2011, our priorities are as follows. In
21 the compliance area, it's to continue to increase
22 participation in the BQMS program. As I said, we have

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Biotechnology Regulatory Services Meeting 12-01-2010

26

1 10 enrolled now. Our goal by the end of 2011 is to
2 have 20 entities enrolled in the program. I think we
3 have a full class already for February, and a number
4 entities have expressed an interest for the class that
5 will follow the February class, and I don't remember
6 the date of that, but we'll cover that this afternoon.

7 Contingent on funding, we also have a goal
8 increase the number of inspections that we perform.
9 have been doing about 500 per year for many, many,
10 years, and we are trying to get that up to about 800
11 because the number of trials that are out there have
12 been increasing. The inspections need to increase, I
13 believe, at a rate that's commensurate with what is
14 there and that we're responsible for overseeing.

15 In terms of the petition process, we'll be
16 implementing a NEPA pilot project. We're revising our
17 standard operating procedures. We're going to
18 establish some preliminary timeframes for key steps in
19 the process. We're going to add more staff and
20 resources including contract resources, and we're
21 to further drill into the nuts and bolts of the
22 using Lean Six Sigma techniques. So those are our

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27

1 priorities for 2011.

2 Some other areas that are of interest to
3 people that I want to make some remarks about although
4 what I can say about these things is somewhat limited.
5 First, the litigation that we're involved in. First
6 all, with respect to the alfalfa litigation and the
7 court order that we prepare an environment impact
8 statement before making a decision on deregulation of
9 GE alfalfa, we did publish this past year a draft
10 environmental impact statement. The comment period
11 closed last March. We got 244,000 comments on that
12 and we're very close now to finishing the final
13 environmental impact statement and publishing that,
14 our intent is to get that publish yet this month.

15 In the sugar beet litigation, there are a
16 number of things going on. In the sugar beets, one
17 case in which the court overturned the Agency's
18 decision to deregulate Roundup Ready sugar beets, the
19 decision the Agency had made in 2005, the court
20 the preparation of an environmental impact statement.
21 The work on the environmental impact statement has
22 begun. We did publish a notice of intent in the

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Biotechnology Regulatory Services Meeting 12-01-2010

28

1 Federal Register and took public comments on the
2 that will be analyzed in that document and the
3 alternatives that would be examined. We have awarded
4 contract for the preparation of that EIS. Work is
5 underway, and we have informed the court that the
6 Agency anticipates completing that whole process
7 including a draft EIS, final EIS, and record of
8 decision by the end of May 2012, and we are on target
9 to complete the process in that timeframe.

10 Also related to the Roundup Ready sugar beet
11 1 case, the Agency published last month a draft
12 environmental assessment for public comment that
13 at three alternatives including one alternative for
14 partial deregulation that would authorize the planting
15 under Agency oversight while the Agency goes about
16 completing a full environmental impact statement. The
17 comment period of that draft EIS closes Monday,
18 December
19 6.

20 And in the sugar beets 2 lawsuit, which was
21 suit that challenged permits that the Agency issued in
22 September for the planting of the seed crop under

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Biotechnology Regulatory Services Meeting 12-01-2010

29

1 permit, the judge yesterday found in favor of the
2 plaintiffs who were seeking to have those speckling
3 plants removed from the ground. That decision was
4 made yesterday. The Department is looking at the
5 judge's ruling and will decide on what an appropriate
6 course of action is once that analysis is completed.

7 One of the concepts, if you will, that has
8 emerged from the litigation that there has been a good
9 deal of interest in is the notion of partial
10 deregulation. In fact the APHIS regulations say with
11 respect to petitions for nonregulated status that the
12 Agency can decide to deregulate in whole or in part,
13 and the Supreme Court ruling and other courts have
14 mentioned this partial deregulation notion. We
15 actually have two requests for partial deregulations
16 that we have published on the APHIS Web site, one for
17 alfalfa and one for sugar beets.

18 In the case of the alfalfa, the Agency has
19 been focused on completing the EIS in the case of
20 beets and EA that analyzes partial deregulation if one
21 option is out for public comment. So the concept of
22 partial deregulation is not defined in the

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

30

1 Different people have different views about what
2 partial deregulation means. I think that will become
3 more clear and will evolve over time.

4 The third lawsuit I want to mention today
5 to do with a permit that the Agency issued for cold-
6 tolerant eucalyptus and just to say that a briefing
7 schedule has been set by the court for that litigation
8 that lays out briefs and declarations the plaintiffs
9 and the Government have to file between now and March
10 11 of 2011 at which point I would assume the court
11 schedule a hearing to examine that evidence. So
12 what I wanted to say about the litigation today.

13 The other thing I wanted to talk about is
14 coexistence. Some of you I know are aware or remarks
15 Secretary Vilsack has made in speeches and visits that
16 he's made out in the country. I don't have a lot I
17 say about this today because this is an initiative
18 is being led out of his office. APHIS is not in the
19 lead on this, but this is an issue that's very
20 important to Secretary Vilsack that he wants to find
21 ways so that conventional biotech and organic can
22 thrive in the U.S. I will also say he's very committed

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

31

1 to approach very important public policy issues like
2 this in a transparent, participatory, and
3 sort of a way.

4 So with that, that's the end of my speech,
5 and I'll be happy to take your questions. Clint, how
6 are we doing timewise?

7 MR. NESBITT: A little behind, but I
8 we can take a few questions if you want.

9 MR. GREGOIRE: Okay. So I'll take
10 some question now, and if we can't get to all of them,
11 we will pick up this afternoon. Keith.

12 MR. KEITH: Hey, Mike, Keith (inaudible).
13 You mentioned 18 new employees. How many of those are
14 going to be biotechs?

15 MR. GREGOIRE: How many of those are
16 going to be biotech? Okay. Well, let's see. We have
17 -- four of those are in policy; seven are in
18 Environmental Risk Analysis Programs; five are in
19 regulatory operations, which is compliance and -- one
20 in the Deputy Administrator's office and one in
21 Resource Management Programs. I hope that adds up to
22 18. So biotechs, that would be seven.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

32

1 MR. KEITH: Thank you.

2 MR. GREGOIRE: Uh-huh.

3 MR. NESBITT: Any other questions for
4 Mike?

5 MR. CLAPP: Steve Clapp with Food
6 News. Is there a -- in the judge's order is there a
7 timeline for destruction -- destroying these sugar
8 beets specklings? Or is this something that you can
9 appeal -- or the Department can appeal?

10 MR. GREGOIRE: Decisions on appeals
11 are made by the U.S. Justice Department. The rulings
12 set some additional briefings are due to the court on
13 this question I think by Monday, December 6.

14 MR. NESBITT: Any other questions while
15 Mike is on the stage?

16 (Pause)

17 MR. NESBITT: Going once. Okay. Let's
18 move on to the next (inaudible) --

19 MR. GREGOIRE: You're going to let
20 off that easy?

21 (Laughter)

22 MR. GREGOIRE: All right. Well,

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

33

1 think of them. I'll be back.

2 (Applause)

3 MR. NESBITT: Our first speaker of the
4 morning to make a formal presentation is John Turner.
5 He's the Division Director of the Environmental Risk
6 Analysis Program. He'll speak for just a few minutes
7 about NEPA. We have three speakers in a row who are
8 each speaking about NEPA-related topics, so I think
9 what I may do is field just a few specific questions
10 about the presentation after each presentation but
11 general NEPA conversation we have after all three
12 talks. That's going to be (inaudible). Okay, John.

13 MR. JOHN TURNER: Very good. Thank
14 you, Clint, and good morning everyone. It's good to
15 see you here. I'm not going to get too deeply into
16 weeds of this thing. We have Craig Roseland who is
17 going to talk to you about how a NEPA document is
18 prepared, and Rebecca Stankiewicz Gabel coming up
19 that to talk about the NEPA pilot project, but I plan
20 more to give you an overview, to give you context for
21 NEPA at BRS and just the current state of play.

22 Our authority, as you all know, is not NEPA.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

34

1 It is the Plant Protection Act of 2000, and NEPA, I
2 hope you understand, doesn't in any way expand the
3 authority we have under the Plant Protection Act, nor
4 does it dictate results. What is does do is require
5 that the Agency review all of the potential
6 environmental impact and that that review is recorded
7 in a publicly available manner, so it dictates
8 procedure, not results.

9 The type of actions that we undertake here
10 BRS, which are subject to NEPA, are, of course, we
11 issue notifications. We issue permits. We issue
12 petitions for deregulation; then of course, there's
13 rulemaking. The type -- the classification of NEPA
14 actions required these can either be categorically
15 excluded. It can require an environmental assessment,
16 or they can require the more detailed environmental
17 impact statement. So the way it's set up our
18 notifications are designed to generally meet the
19 requirements for categoric exclusion. Generally, no
20 NEPA document is prepared for that. Permits and
21 petitions for nonregulated status then require either
22 an environmental assessment or an environmental impact

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

35

1 statement.

2 And one of the points I wanted to make here
3 the other speakers talking about NEPA will be focused
4 primarily on NEPA documents for petitions of
5 deregulations, but please remember we also prepare
6 these for permits and usually about three to four per
7 year -- I looked back -- seems to be the average over
8 the past several year of environmental assessment
9 prepared for permits.

10 In terms of NEPA compliance -- so NEPA's
11 a real focus here at BRS, and there are several
12 for this. One, it's been the subject of litigation
13 against the Agency as Mike referred to; and also, NEPA
14 compliance is starting to consume an increasingly
15 portion of our resources. And finally, we're, of
16 course, committed to meeting the standards of NEPA,
17 taking the hard look, and ensuring that our
18 environmental impacts are examined in such a way that
19 meets the hard look (ph) standard and it protects the
20 environment.

21 In terms of NEPA and our workload -- excuse
22 me, this seems a little hard to get use to here.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

36

1 Historically, BRS staff who worked on NEPA also worked
2 on other aspects of permits and notifications. In
3 other words, the biotechnologist as a general rule
4 worked NEPA and worked on the plant-pest risk
5 assessments and other risk analysis type of activities
6 related to permits and notifications. Our NEPA
7 have increased at a time when other workloads have
8 increasing, particularly the complexity of things that
9 we're getting in. And we've also had an increase in
10 the complexity of permits and notifications in terms
11 number of constructs and number of locations as I'll
12 show you. So they're more complex in terms of the
13 longer numbers of constructs and notifications and the
14 technologies are more advanced.

15 In terms of constructs authorized, you can
16 see here that from 2005 to 2009 it's a tremendous
17 increase from just a few hundred to nearly 6,000
18 constructs. Typically, in the past, we've shown a lot
19 of graphics that showed that over time we issue about
20 the same number of permits and notifications. It
21 peaked out around 1,000 sometimes in the mid-2000, and
22 then in recent years, it's been hovering around 8 or

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Biotechnology Regulatory Services Meeting 12-01-2010

37

1 900. But the story that doesn't tell is how many
2 constructs are contained, so that average has gone way
3 up. Also the number of locations authorized has gone
4 up from 2005 through the present.

5 In terms of complexity, permits,
6 notifications, we're starting to see things such as
7 pharmaceutical plants, industrial plants, so it's been
8 around for a few years. And more recently, genomics
9 libraries, zinc finger proteins, synthetic biology,
10 plants for biofuels, and cisgenics, most of these
11 already seen. The others are technologies that
12 discussions going on about, so this also takes more
13 time.

14 The point of all of this is there's an
15 increased workload at the same time we know that our
16 NEPA documents need to be -- are really scientifically
17 and legally defensible.

18 In terms of what we're doing about it, again
19 -- and Mike alluded to this -- we formed a NEPA team
20 January of 2000. It has three of our experienced
21 members from BRS -- they're from BRS -- who had NEPA
22 experience. They received NEPA training. It's led by

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Biotechnology Regulatory Services Meeting 12-01-2010

38

1 David Reinhold, and there are plans in the next year
2 two to add three more NEPA specialists, so that would
3 be a total of six. We're now using outside
4 to prepare many of our NEPA documents to help us
5 the resources and move these through, and then there's
6 the NEPA pilot project, which is another way that
7 should help alleviate BRS resources, produce higher
8 quality NEPA documents in a timely fashion. And
9 Rebecca is going to talk about this. And we're also
10 collaborating more with other USDA programs.

11 So all of these things are intended to
12 increase the quality and timeliness of our NEPA
13 documents. And with that, I'll conclude. I apologize
14 for all my trouble operating the slideshow.

15 MR. NESBITT: Okay. Do we have
16 questions for John? Otherwise, we can hold them until
17 the end of these three talks.

18 (Pause)

19 MR. NESBITT: Okay. Then let's move on
20 a presentation by Craig Roseland. Craig is one of our
21 Senior Environmental Protection specialists in the
22 newly formed NEPA team, new branch.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

39

1 MR. CRAIG ROSELAND: When I was first
2 asked to give a talk about our NEPA process, I thought
3 to myself "Well, there's certainly others in BRS that
4 have a great deal more experience with NEPA than do
5 But then as I thought about it, I realized that I will
6 be working with many of you -- or some of you -- on a
7 one-to-one basis, so we were developers of products,
8 our NEPA process. It would be nice to have a shared
9 perspective for how BRS actually does our NEPA work.

10 Today, we would like to talk, as the
11 shows -- how NEPA completes -- how BRS completes our
12 NEPA analysis. And we do that because the NEPA
13 to some extent has been changing. I would say it's
14 been a more robust process here and one that perhaps
15 has become more important to BRS as well. The focus,
16 as John suggested, will in fact be on the EA as a
17 response to -- or the EA rather than other actions
18 under NEPA, ESs or categorical exclusions, and this is
19 mainly because this is the most number of EAs we
20 prepared that are related to the petition for
21 nonregulated status.

22 One of the things we'd like to do here is

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Biotechnology Regulatory Services Meeting 12-01-2010

40

1 that we were planning to show that NEPA itself
2 a vision for how government agencies show function
3 respect to the environment and how APHIS is taking
4 these into account as it further develops our NEPA
5 process, and this is, of course, for the benefit of
6 some of you as customers, for our stakeholders, and
7 our whole workload as a Federal agency.

8 Some of the key issues that we are going to
9 focus on today are the value for NEPA in, first of
10 providing transparency. This allows us and our
11 constituents to clearly talk about the new products
12 their potential impacts. Secondly, we do this NEPA
13 analysis because it ensures decisionmakers in fact
14 be well informed about potential impacts. Thirdly,
15 this is an opportunity for our stakeholders, for our
16 public, to provide some input into our assessment and
17 our analysis.

18 The last issues that we'll be discussing --
19 and this my colleague Rebecca Stankiewicz Gabel will
20 presenting -- is looking at some of the new issues,
21 ideas that we will be implementing in the near future.

22 Let's consider NEPA as a process, some of

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Biotechnology Regulatory Services Meeting 12-01-2010

41

1 core issues that really undergird it, and how it can
2 provide APHIS with the tools that we need to benefit
3 U.S.

4 agriculture, our stakeholders, and those at
5 least who participate in its opportunities for input.

6 First of all, let's have a look at a
7 historically view of NEPA and its origins. There are
8 variety of reasons that Congress advanced for why they
9 decided to require Federal agencies to begin to
10 consider environmental issues fully while making their
11 decisions. We're not going to consider the motivation
12 in any details, but really, look at the requirements
13 that they made for this very far reaching national
14 policy for the environment. And it's interesting to
15 note that this statute is now 40 years old.

16 We will see that this is not just a
17 unidimensional requirement with a focus on the
18 environment but that really takes into account a
19 variety of stakeholders and their needs and their
20 interests as well as government agencies and their
21 specific needs as well.

22 The NEPA statute, as you see on the screen,

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Biotechnology Regulatory Services Meeting 12-01-2010

42

1 was signed into law, and that was in 1970 by Richard
2 Nixon, and of course, had a very wide, broad intent
3 a very wide reach. And this has been summarized by
4 Nicholas Youst (ph) to have really two main
5 We can see that efforts taken under NEPA will "Prevent
6 or eliminate damage to the environment." And in Title
7 I, section 1: "While taking these efforts, Federal
8 agencies should use practicable means for harmonizing
9 the need of people with the environment." So we see
10 really is an interactive process taking into account
11 more than just the environment.

12 Secondly, we would say that Federal agencies
13 are required here to give consideration and proper
14 weight to all environmental factors in their planning
15 and in their decisionmaking. I like this quote taken
16 from the Court of Appeals of the District of Columbia
17 Circuit in 1974, which talks about -- this is when
18 was quite young, and they said that the harm against
19 which NEPA's impact statement requirement was directed
20 was not solely or even primarily adverse consequences
21 to the environment. Such consequences may ensure
22 despite the fullest compliance. Rather, NEPA was

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Biotechnology Regulatory Services Meeting 12-01-2010

43

1 intended to ensure that decisions about Federal
2 would be made only after responsible decisionmakers
3 fully adverted to the environmental consequences of
4 actions, and they had decided that the public benefits
5 flowing from these actions outweighed their
6 environmental cost.

7 We need to give some emphasis to the
8 principle that NEPA is basically a procedural mandate.
9 Agencies need to be given -- are given the requirement
10 to consider environmental factors, as we said, that
11 should be assessed when an agency considers any
12 So this policy clearly provides a goal, and that's for
13 preserving and enhancing the environment; also it look
14 for opportunities for care for U.S. natural resources.
15 But the main thing that concerns us is the requirement
16 for this environmental assessment that provides a
17 for Congress and their goal to oversee or to look
18 environmental protection issues.

19 As an agency that embraces the planning
20 perspective for NEPA that was envisioned by Congress,
21 certain benefits are clear. In the process of
22 particularly for and EIS, the interest of

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Biotechnology Regulatory Services Meeting 12-01-2010

44

1 of the public, and of special interest can clearly be
2 determined. So if this process is fully embraced,
3 Congress and the CEQ, the Council on Environmental
4 Quality which was created by the NEPA Act, they
5 envisioned that there would be an opportunity, an
6 atmosphere, for give and take with these constituents
7 and that even partnerships might be forged that result
8 in successful implementation of those Federal actions.
9 They even imagined that collaborations could be
10 established to find solutions for potential impact or
11 possibilities for reducing the likelihood of some of
12 these impacts.

13 As we said, one of the parts of NEPA was to
14 create Council on Environmental Quality. That's in
15 Title II of the statute. And one of their functions
16 was to review and appraise various programs and
17 activities of the Federal Government in the light of
18 the policy set forth in Title I that sets forth what
19 the aim of the statute is for the purpose of
20 determining the extent which such programs and
21 activities are contributing to the achievement of such
22 policies.

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Biotechnology Regulatory Services Meeting 12-01-2010

45

1 There is not actual regulatory agencies that
2 directly oversees NEPA to see whether it's carried out
3 or not, so agencies are basically self-regulating in
4 the way that NEPA is enforced. Consequently, the
5 Council on Environmental Quality notes that the Office
6 of the President, the Federal agencies themselves, and
7 the courts are jointly overseeing the application of
8 this statute. So one might say that this limited
9 oversight that we have is really a benefit to Federal
10 agencies because it gives us a certain amount of
11 flexibility in dealing with environmental issues that
12 we face in pursuing our policies.

13 Beside there is a requirement that's imposed
14 by Congress that the stakeholders should have input
15 into Federal decisions by the relevant agencies
16 NEPA, there is also the possibility that if we propose
17 alternatives that are beyond the scope of the
18 agency that these have potential importance as well.
19 And for example, this provides what we say is a kind
20 publicly reviewed opportunity to seek changes in
21 existing law or the regulations in order to allow for
22 more attractive alternative to be taken by the

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

46

1 concerned.

2 One important point that we need to focus in
3 on as we think about what NEPA is and the regulations
4 that are produced is that their underlying focus is
5 this: Section 1501.1(c) of the regulation has this to
6 say -- and this really is -- I love this because it's
7 so unbureaucratic in its statement of things --
8 "Ultimately, of course, it is not better documents but
9 better decisions that count. NEPA's purpose is not to
10 generate paperwork, even excellent paperwork" -- oh,
11 shocking -- (Laughter)

12 MR. ROSELAND: -- "but to foster
13 excellent actions. The NEPA process is intended to
14 help public officials make decisions that are based on
15 understanding of environmental consequences and take
16 actions that protect, restore, and enhance the
17 environment. So these regulations provide the
18 direction to achieve this purpose." So again, this
19 focus is on NEPA not as a document that we're
20 but really as a thorough process to look at
21 environmental consequences.

22 The third box here, implementing the NEPA

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47

1 regulations, under Richard Nixon, he established
2 guidelines for implementing an EIS that each of the
3 Federal agencies establish for themselves. That
4 progressed under Jimmy Carter. These guidelines that
5 were set for agencies became mandatory through an
6 Executive Order, and they were expanded beyond the EIS
7 to all the procedural requirements of the statute.

8 By 1979, the CEQ had written rules for NEPA,
9 and we understand that these were largely based on
10 codifying existing case law. In 1979 also, the
11 Court held that all the CEQ regulations were
12 and they applied to all Federal agencies, so CEQ
13 regulations those were finished in 1979.

14 But the mission of each of the Federal
15 agencies differs from each of the other ones, and for
16 this reason, CEQ had mandated that each of the
17 create from themselves procedures by which they were
18 implement NEPA. So APHIS has done this -- we did this
19 a number of years ago. In fact for biotechnology
20 assessment, this was done when we were -- the
21 regulations or the biotechnology regulation was in
22 (ph), so this was quite a while ago, but,

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Biotechnology Regulatory Services Meeting 12-01-2010

48

1 they're still useful and valid.

2 The next thing we want to look at is the --
3 some of the main purposes we want to reiterate are
4 important here that we're informing officials and the
5 public where decisions are made for facilitating a
6 means for the public to be involved for assessing all
7 reasonable alternative. And finally, we'll have
8 something to say about how the requirements of NEPA
9 must be integrated with some other things that are
10 included in the NEPA document.

11 But next we're going to look at the types
12 classes of NEPA actions. John has already mentioned
13 some of these in his presentation. Categorical
14 exclusion is the first one, and these are actions for
15 which BRS does not need to produce an EA. So in
16 advance of any specific action, APHIS can determine
17 which procedures, which actions have no significant
18 environmental impact either individually or
19 collectively.

20 But as our APHIS implementing procedures
21 emphasizes does not mean that there are no impacts of
22 such actions but only that such impacts can be

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

49

1 minimized or they can be avoided. They also indicate
2 that the procedures that are associated with these
3 mitigations really are built into the action itself.
4 For example, if we're talking about a permit, a permit
5 has associated with it conditions, and these
6 are meant to provide confinement of the GE organism
7 so that there is a very limited likelihood of any
8 environmental consequence.

9 We are reminded too by CEQ regulations that
10 there may be extraordinary conditions in which
11 categorical exclusion need to have a specific EA done,
12 and they list some of these issues. For example, does
13 the issue become -- is it very controversial; it may
14 need an EA. Are there a greater potential for adverse
15 impact on land, air, water; these may require an EA.

16 In fact APHIS historically has been able to
17 do an EA when, for example, a product has a trait with
18 a very novel apogemid (ph) or there's specific public
19 concerns that have been raised about it or the Agency
20 has little familiarity with the new crop. So in that,
21 we demonstrate that we have considered all the
22 impacts when we decide to do an EA when a categorical

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Biotechnology Regulatory Services Meeting 12-01-2010

50

1 exclusion would have been a possibility and that the
2 steps we have taken are sufficient to confine the crop
3 and prevent any environmental impacts. We should note
4 that categorical exclusions are accessed in advanced
5 any specific issue, and they also have to be
6 by a CEQ in advance as well.

7 The next class -- boy, things move quickly
8 here -- environmental assessment it has to be a
9 public document that provides sufficient evidence that
10 allows us to determine whether we need to produce an
11 environmental impact statement or alternatively the
12 finding of no significant impact, FONSI. In fact if
13 the proposed action does not have significant impacts
14 then this FONSI may be prepared. The EA is also a
15 record that we have completed our environmental
16 responsibilities toward NEPA, an EA could also be the
17 basis for doing an EIS, and we have recently done one
18 of these that will become a basis for an EIS. The EA
19 and it -- FONSI, of course, the typical mean which
20 APHIS proceeds on when we wish to -- or we're
21 responding to a petition for deregulated status.

22 What is a FONSI? This is the summation of

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Biotechnology Regulatory Services Meeting 12-01-2010

51

1 the conclusion of the environmental assessment. This
2 must summarize the EA, provides reason why a
3 of no impact, no significant impact is determined.

4 An ESI is a detailed statement, of course,
5 the environmental impact of the proposed action. We
6 must identify any adverse environmental effects which
7 can't be avoided should the proposed action be
8 undertaken. Just as an EA does, it provides
9 alternatives to the proposed action, and it identifies
10 any possible irreversible commitments of resources
11 are made if we implement the proposed action.

12 Now let's get to the heart of our EA process
13 here. As I said, this is a sequential process. The
14 first thing that is necessary on this pathway is to
15 identify the issues, the relevant issues.

16 The relevant issues are these. For us,
17 determining what are the alternatives, what are the
18 possible impacts, and what are the range of actions
19 that might be considered in this, for example, a
20 petition that comes in. As we think about
21 alternatives, we must remember that the alternatives
22 are the very heart of any EIS, certainly, but an EA as

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Biotechnology Regulatory Services Meeting 12-01-2010

52

1 well. It's a very key section. One of the important
2 things about an alternative is it must meet the
3 and needs of the agency that is taking the action,
4 that's us.

5 So it's going to present, certainly, some of
6 the environmental impacts of the proposal and its
7 alternatives, and they're going to clearly -- we have
8 to be able to clearly identify what options are
9 available to us as an agency. The alternatives have
10 be reasonable ones. We also have to include a no-
11 action alternative. Sometimes we've had to puzzle
12 though over what no action is. It seems like a simple
13 thing, but sometimes we really have to think through
14 what no action might mean in an EA.

15 The draft EA, as you saw in the sequence, is
16 the first thing that we do, and we may not indicate if
17 there are a multiplicity of alternatives. We may not
18 indicate which one we prefer. We don't need to at
19 point, but we will do so in the final EIS.

20 By and large, our EA alternatives are
21 twofold: Basically no action and fully deregulate. As
22 Mike Gregoire discussed, also partial deregulation is

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Biotechnology Regulatory Services Meeting 12-01-2010

53

1 certainly a theoretical possibility and has been
2 considered in very few numbers of our EAs at present,
3 but it's certainly a question that really requires
4 further discussion among ourselves and probably our
5 constituents as well.

6 So we identify the alternatives; the next
7 thing we have to look at is the impacts. These might
8 be direct, indirect, or cumulative. Direct impacts
9 those that are caused by the action and may occur at
10 the same time in the same place. Indirect actions, on
11 the other hand, are those that are also caused by the
12 action but in fact may be further removed in distance
13 or time but are also reasonably foreseeable.

14 To give you an example of what might be an
15 indirect impact was if you came up with a product that
16 resulted in some change in land use that would be an
17 indirect consequence of the product. The product also
18 might create some kind of delayed effects on
19 ecosystems. In a herbicide-tolerant crop, for example,
20 if you're spraying a herbicide, the crop itself is not
21 providing a direct impact, but the use of herbicides
22 rather is providing the impact, so it's indirect.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

54

1 Cumulatives are the last category of
2 and these are defined as incremental impacts of the
3 actions when added to other past, present, or
4 reasonably foreseeable future actions regardless of
5 what agency or what person undertakes them. So in
6 case, you can see something that appears to be
7 relatively minor actions may become significant when
8 they occur collectively over time with other actions.
9 So one cumulative action that we might mention here is
10 the possibility, for example, that looking at the
11 rotation of a number of crops in which all of these
12 crops had the same herbicide tolerance. The impacts
13 a new crop that was proposed that would be used in
14 rotation would have potential for a cumulative impact,
15 and we would need to consider that in our analysis.

16 Now what I'd like to talk about is what are
17 the inputs that we have for the types of
18 that we make for identifying these issues that we know
19 need to be discussed in the EA. First of all, we're
20 going to receive some of our inputs from the
21 himself. Many of our developers certainly are aware
22 before they bring their product in to us of affected

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Biotechnology Regulatory Services Meeting 12-01-2010

55

1 parties that might be interested or have some concerns
2 for the product. They might have some ideas of
3 specific impacts, and we would like our customers to
4 bring those forward in the petition or if not at a
5 later time.

6 The other thing that is becoming
7 important we've added a new focus on providing
8 socioeconomic information that we will discuss
9 potential impacts for, and this includes things that
10 relate to the specialized company itself and the
11 business. We might need industry information. I'm
12 not saying we will definitely, but this may be
13 important as we look at possible impacts of the
14 in the broader context of the socioeconomic realm.

15 I might note that -- and this is something
16 that Rebecca will be talking about next after this
17 -- is that environmental reports may be provided as an
18 option. In fact some of our companies are already
19 producing what amounts to an environmental report in
20 the petition itself discussing these very things,
21 types of impacts that NEPA concerns itself with.

22 We also have way that we receive inputs as

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Biotechnology Regulatory Services Meeting 12-01-2010

56

1 consider possible impacts. Agencies, of course, are
2 encouraged during the planning stages of our actions
3 engage with other Federal agencies that may have
4 concerns about specific environmental issues or which
5 may have some jurisdiction over these issues that we
6 are discussing. In some cases, we are mandated to
7 under the coordinative framework with our colleagues
8 EPA and FDA, and they may provide some input for us as
9 well. But we've also discovered that we have found
10 very useful in consulting with other parts of the
11 farm services, agricultural marketing, natural,
12 program; all of these have been helpful, and we could
13 potentially engage these as cooperators, but we have
14 not done so at the present time.

15 The parts of NEPA that we are focusing on
16 in our NEPA document or EA, of course, are purpose and
17 need. This is a section in which we ask "What is the
18 need to which our agency is responding?" And our
19 purpose and need, of course, are listed first. Our
20 purposes for the most part in APHIS is to protect
21 America agriculture, to improve our agricultural
22 productivity, and our competitiveness. And we also

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

57

1 have a new goal, and this is we assert that all
2 of agricultural production, conventional, organic, and
3 the use of genetically engineered varieties can
4 benefits to the environment, to consumers, and to farm
5 income. Of course, we also state the purpose and need
6 of the petitioner. Affected environment is important.
7 What is the area of the environment that is affected
8 created by the alternatives that are considered.

9 And here I would like to make an
10 encouragement for our petitioners to remember that we
11 would like to limit the affected area as much as
12 possible. If you have a product that, for example, is
13 going to be marketed to a specific area, you need to
14 very clearly establish that. It may be that your
15 product doesn't perform well in certain areas. Or if
16 it's a product that's an oil seed, maybe the specialty
17 oil producers are in a certain region, but make that
18 clear, limit that so that for the reason that if you
19 limit the affect area it limits the environmental
20 consequences section. If we can tie that down to a
21 small area, then we don't have to discuss the larger
22 area in which the product might potentially be sold

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

58

1 really not actually marketed in that area.

2 Environmental alternatives, we've already
3 discussed those. Environmental consequences, of
4 course, we've looking in detail at the alternatives
5 that are presented for this decision. We're looking
6 the scientific and analytic basis for the comparisons
7 of the alternatives that are proposed and what impacts
8 that these might have. We're talking about -- in this
9 section we look at direct and indirect effects and all
10 environmental effects of the alternatives.

11 Now let's look in detail at the resource
12 areas that we must access, and these resource areas
13 brought up first of all in the affected environment
14 section, and then there's a mirror of these in the
15 environmental consequences section. So typically we
16 and also talked about agricultural production. This
17 includes the seed industry, the GE industry,
18 conventional, organic, and specialty crop. Physical
19 environment must be addressed. These issues are water,
20 soil, air, climate; the areas of the animal and plant
21 communities; biological diversity; gene flow; the
22 fourth area of public health, this includes human

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

59

1 health, worker safety, animal feeds. And lastly, an
2 area that we have a greater focus on is socioeconomic.
3 And these include domestic environment, trade
4 and the social environment.

5 So as we step through the issue, we've
6 identifies our issues, we've written our draft, the
7 we solicited public comments. The comments -- and
8 these are not just from the public, of course. All of
9 our industries, our industry associations, academics,
10 specialists in all areas send in comments. Our job is
11 to response to these, and if there is anything that
12 left out of the draft EA, these must be incorporated
13 our final EA, and we also respond separately to these
14 as well in a separate document. We issue a FONSI and
15 publish its availability in the Federal Register.

16 So we're assuming that we've completed all
17 these steps -- and this is my conclusion here -- we've
18 considered all the reasonable alternatives,
19 we've informed our stakeholder; we've informed the
20 decisionmakers about all the possible impacts on
21 biological environment, physical environment,
22 socioeconomic issues; we've encouraged public input

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

60

1 input from all sources; and as I said, we've responded
2 to requirements as well. If you read our
3 assessments, you realize that we have a section on
4 threaten and endangered species. This is not
5 necessarily a part of NEPA. We put it there because
6 it's really part of our responsibilities that we're
7 answering to our requirements of the Fish and Wildlife
8 Service. We also have some Executive Orders which we
9 respond to as well.

10 So that completes our presentation of our EA
11 process in BRS, and of course, I want to encourage you
12 to remember this is a process. We want to focus on
13 this is a process and not as a document. It ends up
14 with a document that's supposed to show that we have
15 considered effectively all these issues, all these
16 possible impacts, all these alternatives, but really
17 it's an interactive process that we as an agency
18 to determine what are the potential for impacts and
19 then determining whether these are significant or not
20 significant; and having done, clearly recorded them
21 make them available to the public. With that, I'd
22 to close.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

61

1 MR. NESBITT: Thank you, Craig. I think
2 in the interest of time, we'll move on to our next
3 speaker. Rebecca Stankiewicz Gabel is also a senior
4 environmental protection specialist in the new NEPA
5 branch, and she'll be making a few remarks about the
6 NEPA pilot program that we're considering.

7 MS. STANKIEWICZ GABEL: Can everyone hear
8 me? I feel a little short behind this podium, so hi.

9 (Laughter)

10 MS. STANKIEWICZ GABEL: I tend to
11 like to wander around while I talk, so I'm going to
12 to speak into the microphone, but if I wander off,
13 point back the microphone, and I'll try to get back
14 here.

15 So I'm going to talk to you very briefly
16 today about a NEPA pilot project that we're going to
17 implementing in the very near future. You can
18 this sort of this is the advertisement or the
19 infomercial for the pilot project yet to come. Really
20 what this pilot project is is it's a way for us to
21 formalize and collect information and evaluate our
22 processes and techniques that we've been implementing

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

62

1 over the last year and to look at some opportunities
2 for new types of tools that we can use to improve our
3 NEPA process.

4 So the timeframe for our pilot project will
5 be approximately two years. It's going to be a
6 voluntary program. You're not required to join the
7 pilot project. However, I would encourage to join the
8 pilot project if you have a petition that falls within
9 the range of time which the pilot project is taking
10 place. The more participants we have in the pilot
11 project the more robust our analysis will be, the more
12 interactions we can have with you and look at ways to
13 improve our NEPA process. There is no limitation on
14 participants, so I encourage you all to join.

15 The goal of our pilot project is really to
16 test new approaches to developing NEPA analyses, to
17 determine the extent to which these approaches can
18 improve the quality, timeliness, and cost of our NEPA
19 document. So overall, it's really just a way to look
20 at efficiencies in our system, look at new tools, and
21 ways that we can interact with you in order to improve
22 our process.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

63

1 The objective, there's basically five
2 objectives to this. One of them is to create
3 mechanisms for early interactions between the BRS team
4 members, so us and you. What we want to do during that
5 interaction is identify potential environmental
6 impacts, things that you might know about just from
7 interacting with your own stakeholders, your own
8 customer, what kinds of things should we be thinking
9 about as we progress through our analysis, and to
10 identify and document information needs from you for
11 to help improve our NEPA process.

12 Another thing that we hope to do through
13 is to create mechanisms for scoping NEPA-related
14 early in the process; early in the process meaning
15 before we put out the draft EA to try to make sure
16 we have all of the issues and we've analyzed those
17 issues as we put out our initial document, and we do
18 that analysis early in the process. And we want to
19 encourage participation for both the applicants and
20 other stakeholders. So again, we're looking at ways
21 encourage those kinds of interactions throughout the
22 process: What do you know? How can you share that

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

64

1 information with us? How can other groups share
2 information with us so that we can improve our NEPA
3 analysis?

4 We also want to create mechanisms for
5 applicants to share information necessary for
6 developing our NEPA documents or NEPA analysis. And
7 one of those mechanisms is something that we're
8 and environmental report. There are petitioners who
9 have submitted environmental reports to us in the
10 and so through this pilot project, we're going to look
11 at little bit at formalizing that, looking at the
12 components of an environmental report and the types of
13 information that you can give to us that can help us
14 with our NEPA analysis.

15 We also want to utilize mechanisms for
16 applicants to share the cost of completing NEPA
17 documents. So as Craig laid out, doing a NEPA
18 a rather lengthy and can be at times a complex
19 undertaking, so we're looking at mechanisms by which
20 you as the applicant can also share that cost. One of
21 the things that we're talking about are -- they're
22 called cooperative service agreements and ways that an

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

65

1 applicant could in some way take on part of the
2 of hiring a contractor and working through the

3 We also through this entire pilot project we
4 really want to measure and examine improvement in the
5 quality and timeliness of our NEPA documents as a
6 result of implementing all of these mechanisms. So
7 again, really, the goal of this is to look at how do
8 these different types -- using these different types
9 tools increases our efficiency, the effectiveness of
10 our documents, and the cost of those documents.

11 So our outcomes are to determine the effect
12 of applicant-prepared environmental reports for NEPA
13 analysis, again, on quality, timeliness, and cost. So
14 having more of a formal mechanism for you to supply
15 information to us how does that increase our
16 or decrease the overall cost of preparing our
17 documentation and determine how applicant-funded NEPA
18 analyses impact agency resources as well. So again,
19 looking at the timeliness, the effectiveness, and the
20 cost of our NEPA analysis.

21 To be eligible for the process, if you want
22 to join the pilot project, basically, you need to have

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

66

1 a petition. We're only doing the pilot project for
2 environmental documents related to petitions. At this
3 time, we're not including environmental documents
4 related to permits, so you need to have a petition.
5 Basically, you can have one now at the start of the
6 pilot project or within the next six months or so of
7 when the pilot starts. We'll be taking people all
8 along throughout the process, but there'll be at some
9 where we're getting near the end in evaluating the
10 data, and so we may not include that information in
11 analysis, in our pilot project.

12 We need to have -- you can have a petition
13 that is already complete and undergoing review.
14 Basically, if we haven't started working on the
15 environmental documentation, that is a good time for
16 you to participate. And this is basically for this
17 part is for environmental reports, so applicant-
18 prepared environmental report. The idea behind that
19 if we've already started doing our NEPA analysis you
20 giving us an environmental report at that point
21 probably isn't going to increase our efficiency
22 we're already talking to you and getting that

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

67

1 information from you.

2 And then you can also submit an
3 report to us if the petition has been incomplete and a
4 plan has risk assessment, is being prepared, but the
5 work on the environmental document hasn't started. So
6 basically, any time from you're thinking about
7 submitting a petition in the next six months to you
8 already have a petition in house it's been deemed
9 complete but the environmental analysis hasn't
10 we talk about submitting an environmental report.

11 And then in terms of applicant-funded NEPA
12 analysis, that you can do at any time doing the
13 process; so even if you currently have a petition
14 that's in house and that petition has a draft EA, if
15 you want to participate in the pilot project and look
16 at funding the analysis of comment or respond to
17 comment or the final EA or any of those steps in the
18 process, those would also be eligible.

19 The kinds of documents that we'll accept.
20 We're looking for applicant-submitted environmental
21 reports. And again, these can be submitted with the
22 petition application or submitted while the petition

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

68

1 under review, or it can also be submitted once the
2 petition is deemed complete and the plant
3 (indiscernible) risk assessment is either complete or
4 underway. And we will use these to prepare our
5 environmental analysis, our NEPA analysis, so it's
6 either an EA or EIS. And again, it's for petition
7 only.

8 We will also be looking for people who are
9 interested in funding through cooperative service
10 agreements, the preparation of NEPA analyses and
11 documentation, and that we can do at any point during
12 the process.

13 Next step. We should be having a Federal
14 Register notice that should be published soon,
15 hopefully, before the end of the year, and we'll begin
16 accepting participants into our pilot project
17 officially in the spring of 2011. That's it

18 MR. NESBITT: Thank you, Rebecca.

19 MS. STANKIEWICZ GABEL: Does anyone have
20 any questions.

21 MR. NESBITT: Yes. If you have any
22 questions for Rebecca about the pilot or about our BRS

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

69

1 NEPA process in general, we've got plenty of time for
2 questions.

3 (Pause)

4 MR. NESBITT: And again, don't forget to
5 state your name and organization into the mic so we've
6 got that.

7 MR. ZEPH: Larry Zeph, Syngenta.
8 Thanks for the presentation. It's was very helpful.
9 wondered if mind a couple of question. First, you
10 comment on -- to those of us who are petition
11 what sort of guidance is available out there now or in
12 the future for opportunities for consulting with you
13 directly in this process?

14 MS. STANKIEWICZ GABEL: So one of the
15 things we'd like to do through the process is through
16 working with you is develop good guidance, guidance
17 that will really be useful for you. And so while
18 in the pilot project stage, we'll be issuing some
19 preliminary guidelines and guidance. We'll be having
20 individual meeting with the participants. We'll talk
21 about the types of data requirements we have and how
22 can put those together and help.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

70

1 We've actually had some meetings already
2 individuals that are looking to prepare environmental
3 reports and the types of information that they might
4 want to submit. Again, what the pilot project is
5 to do is more formalize that process and formalize our
6 collection of information about the process and how to
7 really improve it, make good guidance, and get that
8 to you. So it's going to be iterative throughout the
9 pilot process.

10 MR. NESBITT: Other questions?

11 MR. RAY GILBERT: Ray Gilbert with
12 Monsanto. So a question around timing. If the ardose
13 (ph) comes out by the end the year, are there certain
14 logistical steps that have to take place before you
15 actually formally start the pilot project in the
16 spring? I mean it sort -- it would seem that -- I
17 don't think there's a public comment period which is
18 going to be associated with the notice, so it just
19 seems like a long period of time. It's already been
20 quite a period of time sort of getting the pilot
21 project out. So are there logistical steps that need
22 to happen for the pilot project to actually have

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

71

1 participants enrolled in the program?

2 MS. STANKIEWICZ GABEL: To enroll in the
3 program, yes. If you want to interact with us before
4 that time, then we can still do it the way we've been
5 doing it up until now, which is sort of informal.
6 yes, to set up our measures, we need sometime in the
7 spring and how we're going to actually implement them.

8 MR. NESBITT: Other questions?

9 (Pause)

10 MR. NESBITT: Anyone?

11 (Pause)

12 MR. GIDDENS: Mel (ph) Giddens,
13 consultant. I noticed with interest your language
14 about trying to find cost-sharing mechanisms with the
15 applicants. And while I think this makes a great deal
16 of since in one respect if your applicant is a large
17 company that has the resources to devote, I wonder if
18 you've given any thought about the potential
19 implications of that to very small companies that have
20 a high burn rate or limited access to capital or even
21 perhaps, more importantly, academic institutions that
22 don't have the overhead to support a large expense,

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

72

1 line item for regulatory compliance?

2 MS. STANKIEWICZ GABEL: Well, again, this
3 is -- the pilot project is voluntary. So really the
4 organizations that have the capital may choose to
5 into it, and those that don't may choose not to.
6 However, that doesn't mean that if a smaller
7 organization or an academic institution wants to come
8 in and participate that they can't. They may choose
9 participate more in the role of developing and
10 environmental report or sharing information with us
11 through that mechanism. When you think about academic
12 institutions, those resources are often found within
13 the academic institutions to look at the types of
14 impacts that we're looking at. You might have an
15 environmental sciences department that is -- would be
16 really excited to work on a project that could help
17 with developing and environmental reports.

18 I guess part of this is looking at different
19 mechanisms and looking to be creative and how to
20 maximize resources and create efficiencies.

21 MR. NESBITT: I think (indiscernible)
22 here.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

73

1 (Pause)

2 MR. GREGOIRE: And if I could just add to
3 what Rebecca has said in response to the question
4 because this has been brought up with us before. We
5 are going to maintain and actually plan to increase
6 capacity to develop with our own APHIS resources, with
7 our own staff, or with contract resources at our
8 expense the capability to prepare environmental
9 documents for those entities that choose not to
10 participate in the pilot or aren't able to because of
11 their financial situation. So we're not redirecting
12 resources that might be saved by implementing this to
13 other part of our work. We're going to maintain and
14 increase our capability to prepare these documents at
15 our expense. We've made that assurance to people, and
16 that's our commitment.

17 MR. NESBITT: Okay. Other questions?

18 (Pause)

19 MR. NESBITT: Anyone? Going once?

20 MR. GILBERT: This goes back to -- goes
21 a comment that John Turner had earlier with regard to
22 new technologies which are coming into the Agency.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

74

1 Quite a long time ago, the Agency used to issue
2 documents on when there was something with a new
3 question that a developer had. You mentioned several
4 new types of development, and I'm just wondering
5 whether or not the Agency has, it's been issuing
6 opinion letters or opinion documents on some of these
7 newer technologies and you (indiscernible) of paying
8 in some respect even if it's regulated or
9 and if they have how is that information intended to
10 made public?

11 MR. NESBITT: John, you want to take

12 MR. TURNER: Yes, I'll take it.

13 start and if anyone, Andy, or someone wants add to it,
14 we can. For these new technologies, for the most part,
15 they're still so new, we're still looking at them,
16 investigating. There are a lot of different flavors.
17 At this time for most of them, we're telling
18 they should come in and consult with the Agency, and
19 we'll make our determination of whether they're
20 regulated or not. I think in the future as we gain
21 experience we'll be more prepared to issue opinion
22 letters or possibly some other mechanism in the past

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

75

1 clarify the regulatory status. But because these are
2 new, I think we are developing these technologies, our
3 recommendation at this time is to come in and have
4 conversation with the Agency.

5 MR. NESBITT: Other questions?

6 MALE SPEAKER: -- a break I believe.

7 (Laughter)

8 MR. NESBITT: Okay. If we have no other
9 questions about NEPA issues, we are scheduled to have
10 break next for 15 minutes. We're a little bit ahead
11 schedule at the moment. Before we do break, I want to
12 remind you that if there's anyone in the room who
13 to be registered to use ePermits, we do have someone
14 back there in the back, Steve Bennett, who can get
15 credentials all set up and logged in. We can do that
16 on the lunch break as well, but if you prefer to do
17 that now, he's here. Otherwise, let's take a 15-
18 break, and we'll resume again in about 5 after 11:00.
19 Thank you.

20 (Off the record) (On the record)

21 MR. NESBITT: Hello. If you could all
22 take a seat, we'll be getting start here again

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

76

1 Thank you very much.

2 (Pause)

3 MR. NESBITT: Okay, folks, if you would,
4 please have a seat we'll get started again for the
5 session of the morning. Our next speaker for a very
6 brief presentation and leading a group discussion is
7 Tracy Bowman. She is our new division director of the
8 Policy Coordination Program, PCP, I guess --

9 MS. BOWMAN: That's right.

10 MR. NESBITT: -- acronym.

11 MS. BOWMAN: Yes.

12 MR. NESBITT: And Tracy will be talking
13 about some means of outreach that BRS has and leading
14 the discussion at a group table out the use of our Web
15 site. So with this, I'll turn it over to Tracy.

16 MS. BOWMAN: Thank you. As Clint
17 Michael mentioned, I'm Tracy Bowman, and I've just
18 joined BRS recently as the Director of Policy
19 Coordination, and I'm here to speak out different
20 information mechanisms that you can get information
21 about BRS activities, and for many of you this will be
22 a review, but I think it's just good to have a common

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

77

1 footing for everybody, and there will be some new
2 information here, but some of it will be pretty much a
3 review.

4 What we're going to cover today is sources
5 information on BRS activities, an overview of the BRS
6 Web site, and then we're going to have this activity
7 talked about where we can get your feedback about our
8 Web site, so it will be as useful as it can be.

9 Sources of information. You seem them
10 here. The BRS Web site I'm sure many of you are
11 familiar with that. I just want to mention really
12 quickly though there are some new media tools that are
13 out there that APHIS has instituted, and one of those
14 is Twitter. And for those of you who have used
15 -- I started using Twitter because my teenage daughter
16 went off to college, and I wanted to keep up with what
17 she was doing, and that was a good way to do that, so
18 you that that's a way to get bits of information from
19 the Agency about what's going on. So APHIS does have
20 Twitter feed, and that's a useful thing just to get
21 that sort of summary information, so you can go to the
22 Web site and learn more. And we also have an RSS

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

78

1 and I know from -- I've read transcripts from previous
2 meetings, and one of the comments was, You know, I'm a
3 busy person. I don't have time to go to the Web site
4 each and every day and look at that for hours, and it
5 would be very useful if you could push the information
6 as opposed to me having to pull it. So the RSS feed
7 a really useful way to do that, so I just wanted to
8 mention that really, really quickly.

9 We're also going to talk a little bit about
10 the unified Web site. We're going to talk about
11 performance.gov, and that's probably a new piece for
12 folks. We'll talk just briefly about the stakeholder
13 registry, which you are aware of (indiscernible), the
14 Virginia Tech Web site, the eFOIA reading room, and,
15 course, we'll have a presentation this afternoon about
16 FOIA that's much more in-depth. I'm just going to
17 touch on it, and then I want to tell you a little bit
18 about data.gov.

19 So let's go to the next slide. The BRS Web
20 site, obviously, is intended for stakeholders and
21 public audiences. It has information about petitions,
22 notifications, permits, compliance and inspection

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

79

1 actions, current activities, hot topics, APHIS
2 regulations, Federal Register notices, that sort of
3 thing. So it's a valuable tool for communicating with
4 our stakeholders and the public, and just a resource
5 for you guys, and I've got the URL listed; that's
6 probably nothing new. Next slide, Colleen.

7 The unified biotechnology Web site is
8 maintained by the U.S. Geological Survey on behalf of
9 USDA, HHS, and EPA. It describes the coordination of
10 activities related to biotechnology amongst those
11 agencies. Obviously, it has resources for applicable
12 law and regulations, and there is also a database of
13 completed regulatory reviews. We've been meeting in
14 past and this week as well to look at the data on that
15 site and make sure the integrity is there, the
16 is there. So that's an ongoing effort to make sure
17 that the data on that Web site is the very latest and
18 greatest and so that it's accurate and very useful to
19 you, and there is the URL for that. So it's something
20 we continue to work on, and it's important to us.

21 The next thing I want to talk about a little
22 more that maybe you don't know as much about is some

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

80

1 work that's been going on in this administration as in
2 others about high-performance government. So this
3 administration -- you see the quote there from Obama.
4 Mike talked earlier about transparency. The other
5 thing is about other things that have been an emphasis
6 in this administration is high-performing government,
7 and the President says success should be judged by
8 results, and data is a powerful tool.

9 There are six performance management
10 strategies that have been set up. You see what they
11 are there, but one of those is driving the Agency's
12 priorities and promoting accountabilities. We're
13 to talk a little bit more about that in just a second.

14 So over the last, oh, year or so, the
15 Government has been working on a system or tools that
16 are going to really help drive that accountability and
17 focusing on the top priorities, and one of those is
18 called performance.gov. It's not yet live to the
19 public, but this summer we have been working very hard
20 on that in getting that up to speed, making sure it's
21 accurate, and all that kind of stuff. It's a delivery
22 on the President's commitment to communicate Federal

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

81

1 Government goals. It's a system to drive Agency top
2 priorities. There a set of Agency-specific work called
3 high-priority performance goals or HPPGs, so that
4 terminology may become more familiar to you all over
5 the next few months or so. Each HPPG outlines
6 actions and measures and measures progress toward
7 targets, and OMB is linking the results in HPPGs to
8 budget outcomes.

9 USDA has nine HPPGs, high-priority
10 performance goals. You see them listed there. You're
11 seeing one that's bolded there. That's strength in
12 biotechnology program for genetically engineered
13 plants. That's one that we've been working on. In
14 next few weeks, performance.gov should be going live.
15 You'll see that it's targeted to go live mid-December.
16 We don't have an exact date. I don't want to go into
17 lot of details because we're really still in the
18 process of fine tuning some of the things that are
19 going to make up our measure, the action plans and
20 sort of things, but when you seen it, you can expected
21 to hear the same sorts of things there that you heard
22 from Mike this morning, the things that we have as

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

82

1 priority for 2011. So we've tried to do a really good
2 job at integrating what's in that system with what
3 we've been tracking internally, and I think you'll see
4 that as time goes by. So I think it's going to be
5 performance.gov and be on the lookout for it, and
6 certainly when it goes live, there'll be information
7 our Web site about that. That's been driven from OMB,
8 so we're just -- we're awaiting on the word from them.
9 Stay tuned. Next slide.

10 Just want to make a shameless plug for
11 stakeholder registry. Again, you guys have mentioned
12 that you don't have the time to be going to the Web
13 site all the time, you got busy lives, there's things
14 you're doing, this is another way that we can push
15 to you as opposed to expecting you to pull it from us.
16 So tell your friends, tell your loved one, stakeholder
17 registry, go on the Web site, sign up for that, and
18 news will be pushed to you, and that's the link right
19 there.

20 Biotech query. You guys probably know about
21 that. This is a feature of the BRS Web site. It
22 provides an avenue to get questions answered for

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

83

1 biotech questions. We get questions from many, many
2 people. It's staffed by the communications folks, but
3 they have access to a range of subject matter excerpts
4 across the Agency -- in BRS to get the questions
5 answered. In 2010, we answered 391 questions. Some
6 them were big, some of them were small, some of them
7 perhaps were off topic, but we do answer each
8 and we spend time to make sure we give people good
9 accurate answers, so that's the email address right
10 there.

11 This is the Virginia Tech Web site. I'm
12 many of you seen it or looked at it. It's developed
13 and maintained by Virginia Tech, and it provides
14 information to support the use of agricultural
15 biotechnology products. There's data on development,
16 testing, regulatory review, and there's a search tool,
17 which I think people find very, very useful. So I
18 wanted to mention that, and there's the Web site for
19 that. Next slide, Colleen.

20 I'm not going to talk about this very long
21 because you'll know more this this afternoon, but one
22 other place that people get information is the APHIS

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

84

1 eFOIA reading room. And if you go to any of the Web
2 pages in the APHIS site, at the very bottom --
3 sometimes it very hard to see -- there'll be a teeny,
4 tiny, little where it says FOIA, and that's takes you
5 to the FOIA reading room, and on that site there are
6 multiple FOIA requests and information that provided,
7 and our LPA (ph) staff will be here to tell you much
8 more about that after lunch. Next, Colleen.

9 I wanted to mention really quickly data.gov.
10 I don't know how many people know about it, have used
11 it, or have seen it. This is another open government
12 initiative by this administration to increase public
13 access to high-value, machine-readable dataset. And
14 what does that mean? It means to provide data in such
15 a format that you can use it, tied it to other data,
16 link it, massage it, manipulate it so that it helps
17 do the analysis that are important to you whoever you
18 may be.

19 So if you go to the data.gov Web site, it
20 gives instructions about what the datasets are, how to
21 download them, and up on that Web site are public
22 datasets for permits, notifications, and petitions.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

85

1 you go the next slide, it just shows you a little bit
2 about what it looks like. You can click over on the
3 side that says "Agriculture," and then on that next
4 over there, you can scroll down to APHIS, and you'll
5 come up with a link to an Excel spreadsheet that has
6 our raw data in it. So Steve Bennett wanted me
7 that we're getting votes. It's got five-star rating,
8 people like it, but having said that, I think about 70
9 people have used it; so admittedly, it's probably a
10 small population. But it is a place to get
11 that you can use as you will. It's about 14 MEGS. It
12 takes a little bit to download, but there it is.

13 So what we wanted to do next with the time
14 have left is get your help with the Web site that we
15 have out there now. We've gotten feedback from people
16 that it can be difficult to use docking to navigate.
17 In the USDA's strategic plan that's out there, it does
18 call for an assessment of the functionality and
19 usability of the Biotechnology Regulatory Services'
20 site, so we feel, I guess, honored and privileged that
21 we got a shout-out in the strategic plan. And so we
22 wanted to use the time with you guys here today to

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

86

1 us to respond to this challenge that's in the
2 plan. We've gotten word this week that there are new
3 look and feel design guidelines coming to us in USDA,
4 so in the past, we've followed the USDA's style guides
5 that are out there for Web design, and they've had
6 their structure, and that's for a very good reason.
7 But we're hoping that these new style guidelines will
8 really give us the opportunity to make our Web site a
9 little bit more navigable and a little bit more
10 presentable, a little bit more easier to find things.
11 So we want this tool to be used to you, and your
12 feedback is key.

13 So what we're going to do in your table
14 groups - - and I know some people are sitting sort of
15 almost by themselves, so we may need some folks to
16 of come together because otherwise it might not be
17 a fun conversation. What we want you to do is just --
18 we're going to get these easels that sitting around
19 here. We'd like you to grab an easel and a pen, and
20 there's questions on the right hand side of the
21 handouts we give you, and we've got some questions
22 we'd like you to consider.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

87

1 If you don't remember what the BRS's Web
2 looks like -- and that's perfectly understandable.
3 everybody spends every day looking at it -- we have
4 some pictures here. I'm going to leave it up for you
5 so that you're be able to see them. You may have to
6 come up here, but you'll see that in the center there
7 you have the content, and then you have navigation on
8 the right hand said, and then there's a navigation box
9 here on the left hand side, so just to give you a
10 of what the look and feel looks like. There's
11 applications, regulations, that sort of things.

12 The questions we have in front of you are.
13 Question 1: Do you use the BRS Web site? If yes, how
14 often? If not, why not? Do you use other sources of
15 information? There's a set of questions. So we're
16 asking you to get together and talk amongst yourselves
17 with one of the easel for about 15, 20 minutes, and
18 then we'll report out. So, as I said, what this
19 conversation is going to do for us is get us the
20 feedback we need go to into the next part of what we
21 need to do. And Colleen, you're pointing to me.

22 MS. COLLEEN: Choosing a scribe?

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

88

1 MS. BOWMAN: Oh, yes, choose a
2 -- thank you very much -- choose a scribe. That
3 whoever the scribe is record on easels, and we'll ask
4 that person to come up in front of the larger group
5 just kind of give us a summation of what the
6 conversation was at your table groups. Does anyone
7 have any confusion about what we're about to do?

8 (Pause)

9 MS. BOWMAN: All righty then. So
10 have the questions in your handouts and just spend the
11 next 20 minutes going through that. Thank you.

12 (Off the record) (On the record)

13 MR. NESBITT: Folks, I need you to take
14 your seats please. We're about ready to get started.
15 We are ready to get started.

16 MS. BOWMAN: You guys have warmed
17 cockles of my heart and my staff's heart because this
18 is going to be really, really useful, so I really
19 appreciate. I saw a lot of energy out there, and I
20 like Whoowho! that's great stuff, so we want to hear
21 from each group. So if you could -- well, first of
22 all, I just wanted to say that we want to keep your

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

89

1 sheets on those easels, so don't at the end ball them
2 up and toss them over your shoulders because we're
3 going to use those and transcribe those.

4 But we can just go table by table. If you
5 can put your easel so everybody can see it and just
6 kind of give the groups a sense of the conversation at
7 your table and some key points that you'd like us to
8 take away. And I just want to preface that with
9 that in my history I've built IT systems, so I'm
10 used to people telling me that my systems stink and
11 they need to be better.

12 (Laughter)

13 MS. BOWMAN: So it's -- bring it on.

14 MR. NESBITT: Shall we start over here.

15 MS. NATALIE WEBER: Natalie Weber
16 from Pioneer DuPont. So our group viewed the Web site
17 essentially between one time a week to one time a
18 month. There was variable usage of the Web site, and
19 in terms of the reasons that we looked at the Web
20 a lot of us looked for permits and petitions and
21 notifications status. And many of us are very
22 with the Excel file and download that quite often.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

90

1 In terms of other information, the ones that
2 are listed under question 2 were all reasons we've
3 to the BRS Web site for one reason or another. And
4 then in particular too, we've looked at the work
5 of the BRS organization.

6 In terms of finding info -- and this we
7 recognize too, we didn't want to be too critical, but
8 Web sites often can be confusing, and there are loops
9 and defunct links, but in some cases, there were
10 endless loops, and it was kind of confusing to find
11 information. So in terms of eFOIA, you have to click a
12 few times. It's an iterative process before you find
13 what you're looking for there. In some cases, using
14 the BRS search wasn't quite robust enough to find the
15 information needed, and actually Google helped out in
16 that regard. And then one in, there are dead links or
17 defunct pages, so you have pages there that aren't
18 updated, but there's a new page somewhere else at a
19 different address.

20 In terms of the type of information that
21 like to see updated, the BRS organization chart with a
22 link to names of people. That was something that was

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

91

1 already and quick in the past, and it's now just I
2 think a generic org chart there.

3 And then also with respect to the Excel file
4 that's downloaded frequently, the petition status is
5 longer updated in that file, and so that was something
6 that was fairly useful.

7 MS. BOWMAN: Thank you.

8 MR. NESBITT: Okay. Who's next? Go
9 ahead.

10 MALE SPEAKER: So in terms of the
11 frequency, it varied as well for our group: A few
12 times a week to not so often. We do use a lot of
13 sources such as the ISB Web site, the Federal
14 but as already mentioned, we found ourselves often
15 jumping out of the BRS's Web site and go to Google
16 because just we can find what we were looking for.
17 (inaudible).gov, etcetera.

18 Regarding the stakeholder announcements, it
19 wasn't clear to -- not everybody subscribed to them,
20 but for those who did, it wasn't clear to them what
21 really the purpose was in terms of the information
22 that's shared or frequency. And that was sort of a

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

92

1 theme that we sort of had generally is that there is a
2 lot of information and lots of different ways to
3 communicate it, Twitter, etcetera, but having sort of
4 clear purpose for each one of those sort of channel
5 would be helpful; then you'd know where to go where to
6 go to get different kinds of things.

7 We often use it for similar reasons as
8 already said: Check for permits, guidance, contact
9 information, these kinds of things. And similar, most
10 of the time, it works pretty well. Sometimes the
11 contact information is out of date. Some of the
12 you can run into when looking in particular for maybe
13 regulation or something is you can get in sort of a
14 infinite clicking move where -- we had an example of
15 where you clicked three, four, or five pages deep, and
16 when you finally get to that last page, it could send
17 you back to the middle third page on that --

18 MALE SPEAKER: -- so that was one
19 example that we have. We found that it was difficult
20 to find statutes and the actual regulations, which is
21 where a lot of where a lot of us are going to it
22 quickly. We want to find some piece of language and

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

93

1 couldn't find it. It seemed like there was just too
2 much information, and it needs to be prioritized to
3 serve the stakeholders.

4 Let's see. One comment was that we found
5 Web page a little bit impenetrable, is that that there
6 is so much, and we couldn't get quickly -- when you do
7 a search it doesn't seem like the engine is as
8 sophisticated as our friend Google, so.

9 So it's a lot of information, but is it
10 really useful. And so, you know, we found it best for
11 checking on things like petition status. I'd say that
12 for improvement status we said that maybe ease of data
13 entry for permits. Navigability is obviously very
14 important. And again, having that clear purpose for
15 each one of these communication tools.

16 MS. BOWMAN: Thank you.

17 MR. NESBITT: Who's next? Okay.

18 MS. FITZPATRICK: Hi, I'm Sharie
19 Fitzpatrick with Metabolix. Your table felt that we
20 were primarily users of the ePermits part of the Web
21 site although, again under question 2, all the
22 functions of the Web sites are utilized. We are about

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

94

1 weekly users depending upon the season of the year.
2 The news and information room has also been very
3 useful, and then also we found it through these it
4 would be helpful to have clearly links to things such
5 as regulations.gov for commenting, and about half our
6 table was registered a stakeholder.

7 Question 3 is where we probably spent a lot
8 more time about, again, focusing on the ePermits is
9 that we found that it has been fairly reliable, but
10 although recently perhaps due to loading or something
11 of that nature, it has been difficult to check on the
12 status of some our notifications on permits. So
13 perhaps recently there have been changes made to the
14 system that has affected its functionality.

15 Also, one of the themes was that the contact
16 information for BRS staff is not very transparent;
17 of like you got to know who to know to find a person
18 get to talk too. Again, kind of reiterating this
19 where there was -- the flow chart has been very useful
20 in the past and is not in existence; especially with
21 BRS staff changing function themselves, it would be
22 helpful to have something that after you submit a

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

95

1 notification or permit you know that it's been
2 transferred to someone's care; having something like
3 that pop up in your ePermits Web site so you have a
4 point of accountability would be very helpful for us.

5 Also just general contact information for
6 those at BRS. If there's one area that you have to
7 find for their email and one for their phone number,
8 but sometimes the address is elusive unless you know
9 the area code. So contact information could be a
10 little bit more consolidated into a business card
11 format.

12 The ePermits we felt that functionality
13 be improved. Your staff can push messages to the
14 customer, to the applicant, but we can't push a
15 back through that system. We have to go through
16 which is a separate system, so it would be nice to
17 all of our messages linked into the permit itself, so
18 you can see the chain it's going to take.

19 We felt that the BRS Web site in general
20 would be more helpful to try to cross-link more of the
21 Government Web sites. For example, the U.S. Unified
22 Regulatory page that you just mentioned have not found

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

96

1 that link at the BRS page to kind of step out. Also
2 perhaps links or the search engine be a little bit
3 robust so that it would help us find things out at EPA
4 or official allied services, etcetera.

5 Also, I think that the complaint about the
6 search functioning being somewhat perfunctory is,
7 again, restated.

8 One of the things that using the Web site
9 over the years although it's complex, it's dense, it
10 may not be easy to navigate at least it's the same.
11 once you get the hang of where to go, it's been fairly
12 static; so when you make a change, I think it would be
13 useful to maintain that change so people can learn how
14 to find their way into what they're looking for.

15 And specific to the ePermits, again, it
16 be helpful if you could have multiple notifications
17 open at one time within your account so that you could
18 do a cut- and-paste function because currently other
19 than copying phenotypes or comments, copying the whole
20 permits itself, there's really no way to utilize the
21 information between permits. Also, I think automatic
22 of the TPQ system would be helpful as well.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

97

1 MS. BOWMAN: Thank you.

2 (Pause)

3 MS. STEPHON: Hi, I'm Amber Stephon --
4 Whoa! (inaudible) is fine.

5 (Laughter)

6 MS. STEPHON: Bear with me. Okay. So I
7 decided to do A, B, and C instead of 1, 2, 3. For the
8 first question you had, do you use the BRS Web site?
9 Yes, on a regular basis. Well, from a regular basis
10 all the way down to one time per quarter or to zero
11 actually because I think they don't have many, only
12 so far. These are the resources. We said we didn't,
13 but I remember hearing someone saying Google was also
14 used. And then for stakeholder registry, all of us
15 registered; but for a new stakeholder to able to find
16 where to register at was a little difficult.

17 Do we use the BRS Web site? What is our
18 reason? We also said all of them, and also BQMS --
19 BQMS, and again, we use it for all the reasons.

20 Then we move on to number 3: Are you able
21 find information you're looking for? A lot of quick
22 links occur because once you find it it's hard to go

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

98

1 back and navigate to it again, so that's one way
2 dealt with. And kind of like of search of archives to
3 be better of granted permits. If you had a permit for
4 a -- or if you wanted to make a permit for (
5 indiscernible) and you wanted to look at the condition
6 that it was submitted before, to be able to search and
7 to see what kind of condition that you're going to be
8 under in order to get that permit.

9 Errors: When you're actually submitting an
10 ePermit application, just an error that may pop up
11 you have submitted it. You don't know if it's
12 submitted or not, so who do you contact and how do you
13 get to that information.

14 Also, frequently asked questions. A section
15 would be good of constant log and -- I keep moving
16 (Pause) making noise. And then also a glossary of the
17 terms especially for new users who don't know what BRS
18 is or other acronyms that may be used as well as other
19 terminology.

20 And then for the last one -- oh, I'm sorry
21 the - - What do you like most about the -- most to
22 about the site? Well, the thing we liked the most was

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

99

1 that there's an actual site to go to.

2 (Laughter)

3 MS. STEPHON: So we liked that fact.

4 (Laughter)

5 MS. STEPHON: But of course, we had some
6 suggestions. We would like a cleaner way to navigate.
7 The work charts if they were more updated on a timely
8 basis with possibly contact information to be able to
9 get a hold of those people also their title. More
10 categories maybe instead of only a few and then having
11 to go through multiple layer make more categories
12 there.

13 Like to see -- I guess this one is on to
14 number 5. What would we like to see is that we have a
15 design for mobile devices, and it's kind of hard to
16 this Web site on your mobile device. Also with XML
17 transfers, there are issues with downloading those.
18 And another area we would like to see more in is the
19 12 area. So that's it for me. Thanks.

20 MR. NESBITT: Okay. Who's the -- I'm
21 sorry --

22 MR. GILBERT: Hi, Ray Gilbert with

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

100

1 Monsanto. Generally, all the folks at the table were
2 users and used it frequently, so we jumped more into
3 specific comments on things to improve upon and
4 additional functionality.

5 One of the comments was that the database
6 especially the permit database, sometimes the
7 notification and petition databases seem to get stuck,
8 and they're not updated because the database may
9 actually have been updated, but the Web output of it
10 appears to be stuck in an old, old version. And along
11 those same lines, there is a different file structure
12 that's in place now than it was maybe a year ago or so
13 and that everything used to be behind the /BRS file
14 structure, and now it's behind /Biotechnology. The
15 information is still there behind the BRS, and it's
16 out of date. I mean especially like petitions
17 submitted is old, and it's no longer being updated,
18 you can still get to it, and it looks just like the
19 which is up to date, so that confuses people

20 There is a question or a comment about
21 ePermits with regards to is it similar to something to
22 sort of evening raise with regard to being able

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

101

1 indentify, monitor activities to sort of know who is
2 working on a particular permit or notification at a
3 particular time so that you know who to contact if
4 you've got questions.

5 This is, again, something similar that
6 someone else has raised with regard to guidance
7 documents. There's a lot of guidance documents up
8 there. Some of them are very old. Some are actually
9 probably not relevant or not actually used, so if
10 you're someone who is new and is trying to find out
11 information if you just follow the guidance document,
12 you'd wind up going way off base with regard to
13 practices.

14 The site map is something which is a really
15 valuable tool when you don't know where something is
16 and just sort of have that as up to date as possible
17 because if you don't know which rabbit hole
18 to go down, but if you go to site map, you'll be able
19 to at least look at the entire content of what's

20 Also mentioned was that BRS phone list that
21 was maybe organized by organization that may change
22 frequently if there's staffing changes, but it's a

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

102

1 way to sort of know who's doing what where within the
2 organization.

3 Archiving all regulations, NEPA notices,
4 essential -- we -- I heard that one before with regard
5 to archival material, but it's starting to be a bit of
6 history at BRS, and so being able to find some of
7 older documents is a bit of a challenge these days.

8 An FAQ section was also mentioned before.
9 And I think this was also mentioned by Dan with regard
10 to the key word search or by somebody that -- it
11 doesn't really -- sometimes it gives very, very
12 results especially when you're looking at -- it might
13 be good for you to have just a BRS-only search engine
14 versus an APHIS site generally search engine, so you
15 know where you can narrow it down with regard to what
16 specific part of that APHIS universe you just want to
17 look at.

18 MR. NESBITT: Thank you.

19 MR. MICHAEL HALL: Mike Hall, Monsanto.
20 There's quite a range of usage level in our group from
21 once a day to once a year. Other sources of info, bio
22 came up. About half of us at the table are registered

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

103

1 as stakeholders, BRS stakeholders. And those we did
2 get those announcements said, yes, they are useful and
3 in general they're more digestible than the same
4 information on the Web site.

5 The main reasons for using: Applying for
6 permits, getting documents particularly petitions,
7 finding the status of our petitions, and public
8 comments on petitions.

9 Can we find info? Yes, if you look for it,
10 if you look long enough generally find it. And then
11 getting right to the crux of it, likes and dislikes:
12 Difficult to navigate. So nothing new here. And as
13 commented earlier, a lot of it is related to issue of
14 site maps, key word searching, search tools. Current
15 things are not always current, not always updated.
16 Quality controls: Sometimes there are mistakes in
17 documents or wrong documents behind a link.

18 Positives: Generally, it's well organized.
19 The petition page particular, which we seem to have
20 most experience with. And there's lot of info in
21 contrast to the other agencies involved with
22 biotechnology regulation. You can definitely find

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

104

1 more on the USDA site.

2 MS. BOWMAN: Thank you.

3 MR. JEFFREY BOTTOMS: Hello, my name
4 is Jeff Bottoms with Syngenta. And at the table, our
5 use rate was -- sorry -- (Laughter)

6 MALE SPEAKER: That's okay.

7 MR. BOTTOMS: Our use rate was as a whole
8 pretty low. Pretty much the only thing that we use
9 Web site for in general was to look at notifications,
10 permits, or petitions statuses. We did note that
11 Virginia Tech we found much better for getting
12 information as a whole about the (indiscernible) as
13 compared to the BRS Web site. We did discuss the
14 stakeholder registry, and everyone who has signed up
15 for it liked that information. It's a great way to
16 the small stits (ph) of information then to be able to
17 dive in to more detail on the BRS Web site later.

18 I'll sort of discuss 1 and 2 together. The
19 recurring themes that pretty much all of our
20 discussions was that the organization is not
21 necessarily clear in all the sections. Sometimes it
22 seemed to be activity based, and sometimes it seems to

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

105

1 be form based, and we sort of migrated toward one of
2 the fundamental issue is who's your target audience
3 this Web site. Basically, different user groups would
4 really benefit from different organization of the Web
5 site; and some of the examples we came up with is if
6 you've got someone who's just curious about what's BRS
7 do in general, well, here's that set of information.
8 But if you've got somebody who needs to dive in on a
9 regular basis and look for very detailed, very
10 minutiae, it would stand for very difficult
11 organization in those two groups.

12 MR. NESBITT: Okay. The last group --
13 Thank you.

14 MS. BOWMAN: May I interject here
15 really quickly. I find this really fascinating the
16 person who spoke next is the person who next Monday
17 will be joining the staff and who will have some
18 responsibility for working out all the things that you
19 guys have thrown out there.

20 (Laughter)

21 MS. BOWMAN: So this is a really
22 great -- but this is Dick George, and he joins on

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

106

1 Monday, and he comes with a wealth of experience in
2 communications -- I'd love to tell them the story --
3 for those of you who live in this area and know that
4 commercial for the kids about helping the power lines
5 and with the scrunchy -- he worked on that --

6 (Laughter)

7 MS. BOWMAN: -- and got an Emmy --
8 received some Emmys for that, so has a wealth of
9 experience in communication, and we're really looking
10 forward to having him. I don't know how they roped
11 into this, but --

12 MR. GEORGE: Well, thank you very
13 much for that impressive introduction. Our group
14 actually were fairly light users; only three of us,
15 one of them has abandoned them already.

16 (Laughter)

17 MR. GEORGE: Very light users of the
18 site, and so like the (indiscernible) up here, and I
19 basically myself use the site just to try to learn
20 about what biotechnology at BRS is all about for the
21 last few days and undoubtedly a lot more before Monday
22 when I start my new job.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

107

1 The general feeling the way it was used the
2 most was as a resource. Keith who was here goes to
3 site as an informational resources when he needs to
4 present presentations for various kinds of things. He
5 also had a question that he went to the site to try to
6 the answer. The question was how many deregulated
7 traits have been commercialized? He was hoping he
8 could get an answer to that at the site but was unable
9 to. He was also unable to find it anywhere else, but
10 that's a kind of valuable information that he for one
11 was looking for.

12 Generally speaking, the feeling was that the
13 information that you're looking for is generally there
14 if you have to look around a little bit for it, so the
15 strength is that the information is there. There was
16 general feeling that sometimes it takes too many
17 to get there; also that it takes a few clicks even
18 to get to the BRS site in the first place. Of course,
19 some of those may not be fixable, and that was readily
20 recognized in the group.

21 As far as content, there was a feeling that
22 maybe some links to other databases would be helpful,

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

108

1 but that's something that was suggested. There was a
2 feeling that the site just from a graphics standpoint
3 is not terrible inviting. There is not a lot of --
4 there's just not a lot of eye candy there. I'm
5 thinking that there must be some gorgeous images to
6 illustrate some of the content that could be worked in
7 to make it a little more inviting from a graphics
8 standpoint.

9 Also although all the information is there,
10 and there is a wealth of it, there are no people
11 It feels a little cold, and I think that there are a
12 lot of hard working human being that are making all
13 this kind of thing happen that have possible some
14 relevant things to say about aspects to this that
15 be worked in there that would make it a little more
16 inviting, a little friendlier, and a little bit more
17 effective. Have I covered everything? I think that's
18 about it.

19 MS. BOWMAN: I'd like to thank you
20 all again for being as candid as you are. I think
21 you've hit on some really key points. As I look at
22 this stuff, I seem some stuff that really is low-

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

109

1 hanging fruit, and I think that stuff we could do
2 away, and I see other things and I sort of scrunch up
3 my face, and say, "Well, that could be a little harder
4 and take longer." So what I'd like to do is we'll get
5 this stuff transcribed, and we'll start working --
6 we'll start -- we -- my mom says when I say we I mean
7 you.

8 (Laughter)

9 MS. BOWMAN: We will start working
10 together to figure out what those things are that we
11 can get at right away, look at the new style
12 that are coming from USDA and see how we can implement
13 -- bring those in and start to work on what we can get
14 fixed.

15 Some of you over here -- which table it was
16 - I don't remember -- was it here? Somebody hit a
17 really fundamental -- the fundamental issue is who's
18 your target audience, and that's something that's just
19 -- that is right on the money. So whose interests are
20 -- or whose needs are we trying to address, and that's
21 something that we've talked about internally that this
22 is a question we really need to think about really

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

110

1 sooner rather than later so that we can get to some of
2 these -- all these other things. So I really
3 appreciate you guys sort of nailing it right on the
4 head. So, again, lots of great ideas and great
5 suggestions, and you'll be even hearing more from us
6 about what we're going to do to be making some
7 improvements. So thank you very much for spending the
8 time to give us your candid feedback. And with that,
9 I'm not going to stand in the way of lunch any longer.
10 Hand it back to Clint.

11 MR. NESBITT: Thank you. So we've now
12 reached the end of our morning session. Lunch has
13 arrived, so if you ordered a box lunch, it should have
14 your name on the end the box, so look through and find
15 the lunch that's to you. If you didn't order lunch,
16 the cafeteria is open, so you are welcome to eat
17 there or here, and we will reconvene at 1:45. And
18 again, one more thing: If you intended to register
19 ePermits, that will also be available throughout
20 so see you back in about an hour and a half.

21 (Off the record) (On the record)

22 MR. NESBITT: Please take your seats, and

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

111

1 will do the afternoon session shortly.

2 (Pause)

3 MR. NESBITT: So our first speaker for
4 afternoon is Anastazia Taylor from the Agency's FOIA
5 office and will be here to give a presentation on FOIA
6 and how we do things here at APHIS.

7 (Pause)

8 MS. ANASTAZIA TAYLOR: Can you hear me?
9 Okay. My name is Anastazia Taylor, and I'm the project
10 manager for the Freedom of Information Act Office, and
11 today I'm going to give you an overview of the Freedom
12 of Information Act. Very informal, so if you have any
13 questions, you can ask me as we go along. As a part
14 the overview, we're going to review the FOIA basics,
15 the electronic FOIA, and transparency and confidential
16 business information.

17 FOIA Basics. What is the Freedom of
18 Information Act? The FOIA established the public's
19 right to obtain agency records from the Federal
20 Government. Any person can file a FOIA request that
21 a U.S. citizen, foreign nationals, organizations,
22 associations, and state and local governments.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

112

1 Which agencies comply with the FOIA? All
2 agencies within the Executive branch of the Federal
3 Government including the Office of the President are
4 subject to the FOIA. State, local government, the
5 courts, Congress, private citizens, and corporation
6 not subject to the FOIA.

7 (Pause)

8 MS. TAYLOR: Is that better?

9 GROUP RESPONSE: There we go. Oh, yes.

10 (Laughter)

11 MS. TAYLOR: What are agency
12 Agency records are records created or obtained by an
13 agency, and they include paper documents, tapes,
14 photos, electronics, and electronic records. Federal
15 agencies must review records to disclose information.
16 However, disclosure is not absolute. There are non-
17 FOIA exemptions to protect information from

18 Exemption 1. Exemption 1 allows us to
19 withhold information authorized by an Executive Order
20 or classified security information.

21 Exemption 2 allows us to hold internal
22 personnel rules and practices including trivial

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

113

1 administrative data and information that would risk
2 circumvention of agency rules, regulation, and law.

3 Exemption 3 allows the Government to
4 information exempt from release from other Federal
5 statutes.

6 Exemption 4 allows us to withhold
7 confidential business information and trade secret
8 information, and this is the exemption that applies to
9 most of your information, and we're going to talk more
10 detail about that later on in the presentation.

11 Exemption 5 allows us to hold inter- and
12 intragovernment privileged material including
13 predecision or advice, opinions, recommendations,
14 attorney-client communications, and attorney work
15 product.

16 Exemption 7 is our law enforcement
17 and it allows us to withhold law enforcement
18 information but only those where release could
19 interfere with enforcement proceeding would deprive a
20 person of the right to an impartial adjudication;
21 constitute and unwarranted invasion of privacy; would
22 disclose law enforcement techniques, methods, and

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

114

1 guidelines; could endanger the life or physical safety
2 or any individual.

3 Exemption 8 allows us to withhold
4 that is contained or released or related to the
5 examination, operating, or condition report prepared
6 an agency responsible for regulations or supervision
7 financial institutions.

8 Exemption 9 allows us to withhold
9 that is geological information and data including maps
10 concerning --

11 Transparency and FOIA. President Obama
12 "A democracy requires accountability, and
13 accountability requires transparency."

14 Achieving Transparency. eFOIA requires the
15 Government agencies to proactively post information on
16 line, and when we say proactively post, that means to
17 post information even if we haven't received a FOIA
18 request for that information. We must also anticipate
19 interest in agency records, utilize technology
20 and the Web, and increase the amount of information on
21 the agency's eFOIA Reading Room.

22 What is the purpose of the eFOIA Reading

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

115

1 Room? It creates informed citizens, quickly provides
2 information to the public, and satisfies public
3 and the public does not have to make a FOIA request to
4 get the information. If that information has already
5 been requested by someone and is posted on our Web
6 site, the public can just go there and download the
7 information.

8 How does APHIS proactively disclose
9 information? We routinely make certain types of
10 available to the public for inspection and copying.
11 This is where our program offices are posting records
12 to the FOIA Reading Room. We ensure the records are
13 available and in our electronic reading room.

14 What should be placed in the FOIA Reading
15 Room? Final opinions, and those are opinions that
16 legal weight; policies and interpretations, and those
17 are policies and agency decisions which have been
18 adopted the agency; staff manuals and instruction, and
19 those are our administrative manuals that relate to
20 public; hot topics, these are where we have had
21 frequent request or we believe there is a significant
22 public interest; and discretionary disclosures, this

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

116

1 where we post information without waiting for a FOIA
2 request.

3 The benefits of transparency. Transparency
4 provides the public a better understanding of APHIS.
5 It increase our stakeholder engagement and
6 collaboration, and it increase access to information.

7 BRS and Transparency. In fiscal year 2010,
8 out of the 708 FOIA requests received by the Agency,
9 of them were for information that related to BRS. In
10 fiscal year 2010, the FOIA office closed 48 BRS
11 requests, which equaled approximately 12,000 pages of
12 records. Requestor asked for information such a
13 petitions, permits, and notifications.

14 What does our FOIA Reading Room look like?
15 We have a snapshot here of what our FOIA Reading Room
16 looks like, and if we have time at the end of the
17 presentation, I'm going to take you live to our
18 room, so you can learn how to maneuver around if you
19 want to view any request that have been posted. If
20 go onto the APHIS Web site and you hit the radio
21 down at the bottom that says "FOIA," it will bring you
22 to our FOIA Web site. This gives you the FOIA contact

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

117

1 information, our address, phone number, and fax
2 Over to the right, if you were to click on
3 the eFOIA Web site, it will bring you to this page.
4 Midway in the page, you see where it says "eFOIA
5 Request." You would then click on that, and it will
6 bring you to the actual FOIA Reading Room, and you
7 select the year that you want the FOIA request. This
8 says "2010" because that's where we're beginning
9 posting from 2010 forward. You will hit "2010" or
10 whatever year applies to the request you want, and it
11 bring you to all our program offices that have records
12 posted to the Reading Room. We're going to choose
13 for this example. And this is where you see all of
14 records that have been requested from FOIA requestors
15 relating to BRS.

16 eFOIA and confidential business information.
17 How does APHIS obtain confidential business
18 information? Business submitters are required to
19 provide the Government with information, and when we
20 say required, we mean required by law, regulation,
21 Executive Order; and this usually goes to contracts,
22 licensees in some type of regulatory oversight.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

118

1 Business submitters also voluntarily give agencies
2 information, and this is usually done with vendors who
3 voluntary give the Government information when they
4 attempting to acquire a Government contract.

5 How does FOIA protects CBI? Exemption 4 of
6 the FOIA protects from disclosure trade secrets, and a
7 trade secret is a commercially viable plan, formula,
8 process, or device. It also protects commercial or
9 financial information obtained from a person which is
10 privileged or confidential. The exemption also
11 protects the interest of the Government and the
12 business submitter. It encourages submitter to
13 Government with reliable and accurate information. It
14 protects information that will cause competitive harm.

15 Exemption 4 partnering with business
16 submitter. The Government must advise a submitter
17 any FOIA request if the agency believes that
18 information could cause substantial competitive harm.
19 We must ask the submitter whether disclosure of the
20 information cause substantial competitive harm. The
21 Government recognizes that they have to work with
22 business submitters. That is why we implement the

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

119

1 submitter notice process.

2 We provide the submitter with a copy of the
3 request and the record request. We advise the
4 submitter to identify any information that should be
5 protected under Exemption 4. We require the submitter
6 to detail in writing how release would adversely
7 competitive position or commercial interest. We
8 the submitter a reasonable time period to provide
9 written justification, and the Agency evaluates the
10 submitter's comment.

11 If APHIS completely agrees with the
12 submitter's comment, the Agency will withhold the
13 requested information. However, if APHIS does not
14 agree with some or all of the submitter's comment,
15 APHIS will explain in the Letter of Intent why the
16 responsive record will be disclosed. The Agency will
17 advise the submitter of the date the information will
18 be disclosed, and this gives the submitter an
19 opportunity to go into court to keep the Agency from
20 releasing information that the submitter wants
21 withheld.

22 The submitter notice process is governed by

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

120

1 Executive Order 12600. If the Agency does not hear
2 from the business submitter in the designated date
3 is in the submitter's notice, we will presume you have
4 no objection to the release of your information. With
5 (indiscernible), APHIS must make an independent
6 decision on whether to withhold the responsive
7 information; in other words, FOIA has the final
8 decision on what information will be withheld under
9 Exemption 4. Have any question?

10 (Pause)

11 MR. NESBITT: Do we have any questions
12 our speaker?

13 MR. GILBERT: Point of clarification.
14 had indicated that there had been 33 requests that had
15 been made via the FOIA office related to BRS --

16 MS. TAYLOR: Yes.

17 MR. GILBERT: -- in, I guess, fiscal year
18 2010.

19 MS. TAYLOR: Yes.

20 MR. GILBERT: But then on the 2010 Web
21 site, there are listed -- there was three documents
22 listed. Is there a procedure or policy in place that

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

121

1 specifically is written down that say when documents
2 will be placed in the eFOIA Reading Room? Because
3 there's a big difference between 33 items requested
4 three documents actually being posted upon the --

5 MS. TAYLOR: Okay --

6 MR. GILBERT: -- EFOI Reading.

7 MS. TAYLOR: In response to the
8 part of your question where it has three FOIA requests
9 listed, that's just a snapshot of the database; and at
10 the time that that snapshot was shown, that was the
11 second or the third quarter, and there were only three
12 there. Currently, in our Web site, there are more
13 posted.

14 MR. GILBERT: There's three as of
15 yesterday.

16 MS. TAYLOR: Well, as of this
17 morning, it's more. We had some -- because we do it
18 and the second part of your question, you asked is
19 there anything in writing. No, but what I can tell
20 is we post to our Web site quarterly. The goal is to
21 post quarterly.

22 MR. GILBERT: Okay, I'll -- You also

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

122

1 mentioned discretionary disclosure.

2 MS. TAYLOR: Yes.

3 MR. GILBERT: Is there a policy on the
4 discretionary disclosure, and do you consult with BRS
5 on which documents should be discretionarily

6 MS. TAYLOR: Tonya, you want to
7 answer that?

8 MS. TONYA WOODS: Actually -- I'm
9 sorry -- Actually any request that we close out in
10 FY'10 we will post. So it depends on what folks ask
11 for. So if they ask for a certain company's
12 information and we get it finished within that year,
13 will post it for that year.

14 MR. NESBITT: Tonya, would you mind
15 introducing yourself --

16 MS. WOODS: Oh, yes, I'm Tonya
17 I'm the Director of the Freedom of Information Act
18 Office.

19 MS. FITZPATRICK: A question
20 regarding the -- this is Sharie Fitzpatrick, Metabolix
21 -- the three that you showed up there if you were to
22 click on them, what type of information -- is that

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

123

1 response or is that the actual request for the
2 information?

3 MS. TAYLOR: It will show the
4 letter, the response letter, and the actual responsive
5 records that went to the requestor.

6 MS. FITZPATRICK: And is there a
7 separate area that you can see sort of the in-progress
8 requests that are alive in your office?

9 MS. TAYLOR: No, there isn't.

10 (Laughter)

11 MS. COATS: -- lost my train of thoughts.
12 (Pause) (Laughter)

13 MS. TAYLOR: We're going to take a
14 look at Web site so that you can understand how the
15 records are posted there if you haven't gone on and
16 seen them before.

17 MS. COATS: Yes. It's actually related
18 what Ray was saying, the discretionary (inaudible).
19 From petitions or notifications is there information
20 that you would feel like you could release without
21 letting the petitioner know ahead of time because you
22 think it would just be of interest to the public

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

124

1 without consulting with the submitter?

2 MS. WOODS: The point of the submitter
3 process is to engage you all -- I mean because these
4 are the record, and they do contain confidential
5 business information that would be proprietary to you.
6 And so, we always have to -- we have to go to the
7 submitter, and we also have to inform the FOIA
8 requestor that we have done so. It's required by the
9 Executive Order. Once we do that, we give you an
10 opportunity to weigh in on what would be proprietary
11 you, so it's a very important process that we partner
12 with you all in order to get these documents reviewed
13 in order to protect you, really; and you have a unique
14 opportunity that other people don't. This is the only
15 part in the FOIA where you actually get an opportunity
16 to weigh in on the Government's decision of how your
17 records are released.

18 FEMALE SPEAKER: (Off microphone)?

19 MS. WOODS: We wouldn't -- we will always
20 come back to the submitter first to make a
21 determination. We've had significant litigation when
22 haven't gone to the submitter, and we end up having to

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

125

1 go anyway; so we wouldn't just put the documents up
2 without consulting with you first.

3 FEMALE SPEAKER: Yes.

4 MR. NESBITT: Other question?

5 MALE SPEAKER: (Off microphone)

6 MR. NESBITT: Okay.

7 MS. FITZPATRICK: All right. Just
8 follow up then. When you say discretionary posting is
9 that in response to a request or not in response to a
10 request?

11 MS. WOODS: It's -- can everybody hear me
12 because I'm the record?

13 (Laughter)

14 MR. NESBITT: Can the court reporter hear
15 you? Okay.

16 (Laughter)

17 MS. WOODS: There's actually both.
18 Discretionary -- sometimes we have FOIA request -- I
19 mean not FOIA request -- we have FOIA requests we're
20 going to post the FOIA responses. But we have some
21 documents -- and not just -- not necessarily in BRS --
22 but in other parts of the Agency that are frequently

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

126

1 requested, and it makes better sense to go ahead and
2 release that record, and that's what we've done with
3 other program; not necessarily with BRS because of the
4 nature of the type of records that you turn in, don't
5 always -- it's not conducive to that as much because
6 of what's maintained in the information. So I think
7 the biggest issues that we try to protect your
8 proprietary information and have you weigh in on it.

9 MS. FITZPATRICK: Thank you.

10 MR. WILLIAM HOWIE: William Howie,
11 BASF. So once a submitter sends our response back to
12 you of what we think ought to remain confidential --

13 MS. WOODS: Yes.

14 MR. HOWIE: -- do you send us some
15 indication back that you've accepted what we've want
16 remain confidential or we if we don't hear from you
17 then we just assume it's finished?

18 MS. WOODS: You will always hear from us.
19 Once you weigh in, you highlight your records, you
20 us what's confidential, we actually write you a letter
21 agreeing or disagreeing depending on portions of the
22 records. You get to see a full-redacted copy as how

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

127

1 will be released. If you do not agree with us, you
2 still take your petition to court and enjoin the
3 from releasing the records if you feel like we've made
4 a -- the Agency has not made a correct decision. So
5 you still have due process rights all the way until
6 court can hear your -- and make a decision, hear your
7 issues and make a decision.

8 MR. NESBITT: Good. Another question?

9 MALE SPEAKER: How do you determine
10 who you contact of the submitter and how long of a
11 the submitter has to respond or comment?

12 MS. TAYLOR: We usually give a
13 submitter 10 day to respond, and we go back to the
14 program. If we have a problem determining who the
15 submitter is, we will go back to the program to find
16 out who that is.

17 MS. WOODS: But I think on the petition
18 this is very clear. I mean you have the company name.
19 It's very clear who the submitter is.

20 MS. COATS: A lot of questions. If you
21 get repeated requests for the same document --

22 MS. TAYLOR: Uh-huh.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

128

1 MS. COATS: -- and you -- so would you
2 notify the submitter every time or just the first time
3 and then -- because then it's eventually it's out on
4 your eFOIA site or something then we wouldn't find out
5 if there were more requests?

6 MS. TAYLOR: Once we get agreed-upon
7 redactions to the document and it's posted to the Web,
8 we will not notify you again because it's in the
9 domain at that time.

10 MS. COATS: The information that's -- but
11 the second request -- the second FOIA request.

12 MS. TAYLOR: Just so you would know
13 who was making a FOIA request for your information is
14 that what you mean?

15 MS. COATS: Yes. Uh-huh.

16 MS. WOODS: The answer is no. We would
17 typically refer that person directly to the Web to
18 obtain it. Say you wanted a reconsideration of the
19 redaction you would -- I mean -- just because we
20 withheld information doesn't mean that a requester can
21 say, "Oh, I want to -- I don't want to see this type
22 version." They can have us re-review it. That doesn't

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

129

1 usually happen. People are generally -- they'll just
2 go to the Web and get the document.

3 MS. COATS: Yes, but the -- a petitioner
4 wouldn't necessarily know who all is requesting their
5 information --

6 MS. WOODS: No.

7 MS. COATS: -- only the first one?

8 MS. WOODS: That's true, but if you want
9 to know who request your information, you could submit
10 a FOIA to see who ask for your information.

11 (Laughter)

12 MS. WOODS: And it's -- but people
13 actually do submit FOIAs to see who's request --

14 MS. COATS: -- request.

15 MS. WOODS: Yes, I get several requests
16 the BRS FOIA log, so people do submit FOIA to see
17 asking for their information. And FOIA requesters
18 don't have a presumption of privacy. That's been
19 litigated on, so we will give you that information if
20 you want to know who's asking for your records.

21 MS. COATS: And one other question. So
22 the past we've -- at least in my experience -- we've

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

130

1 been advised by USDA or BRS staff that if it's easier
2 and more conducive to a speedy review to not claim
3 thing CBI from the get-go from the time of submitting
4 petition, and that if something were to be FOIA then
5 we'd know about it. Is it now better to claim things
6 CBI from the get-go and how would that affect the
7 review process because I think it matters in terms of
8 how easily you can distribute things to people who
9 review? And it's not in our interest to hold that up
10 or to show that down, of courses; but then, we don't
11 want to freely share all the information either with
12 competitors or other entities.

13 So there's a CBI for different categories,
14 to speak, that's like the EPA where you can claim
15 things at different levels of confidentiality in terms
16 of competitors versus general public versus
17 multinationals, and there is no such -- MS. WOODS:

18 Well, there's no --

19 MS. COATS: -- for USDA?

20 MS. WOODS: Well, you have like a load of
21 questions. As far as confidential business
22 in a FOIA, there are no layers of the public versus

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

131

1 other companies versus whatever. Once we give the
2 documents out to anyone, then those documents have
3 made publicly available, so we look at the documents,
4 and we don't care who the requester is, so we don't
5 make a distinction in between requesters type. So we
6 will review it the same no matter what.

7 I don't know -- maybe Cynthia you can weigh
8 in - - on how you like your documents submitted to
9 I'm not quite sure.

10 MR. NESBITT: And if you could, introduce
11 yourself . . .

12 MS. CYNTHIA ECK: So I'm Cyndi Eck,
13 and I'm the Document Control Officer, and I'm sort of
14 the other half of dealing with Tonya's shop. When
15 FOIA request comes in, I'm the one that determines
16 which documents are responsive to this FOIA request.
17 So typically, you're right, in the past your petitions
18 -- most companies do not make claims of CBI, and the
19 reason we've seen this is because we know when that
20 petition then gets posted on our Web site for public
21 comment it's published in full unless there is
22 something claimed to CBI; and then of course, we would

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

132

1 withhold that information.

2 So there's no real difference. The only
3 difference is that we are starting to see an increase
4 in FOIA requests for petitions prior to they being
5 posted on our public table. That's the difference
6 right now.

7 MS. WOODS: And how many did you say
8 had, 13 of the --

9 MS. ECK: We have -- out of the 20
10 pending petitions that we have right now, 13 have been
11 requested prior to they being published, so --

12 MS. COATS: Yes, that's huge. At the
13 that it needs to get posted on your Web site, you --

14 MR. NESBITT: Go to the micro- --

15 MS. COATS: Sorry --

16 MR. NESBITT: It's all right --

17 MS. COATS: -- I thought it was --

18 MR. NESBITT: -- (inaudible).

19 MS. COATS: At the time it gets published
20 usually, first of all, the petition has been deemed
21 complete, so it's gone through a certain review and a
22 certain process or even, you know, it's been based on

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

133

1 so-called approved of what product that's the subject
2 of the petition is deregulated at which point it might
3 be okay to disclose certain information that you don't
4 want to have disclosed before the file is even deemed
5 complete or there's been deregulation, and that's the
6 very point where --

7 MS. ECK: I think then every company
8 should --

9 MR. NESBITT: (inaudible) --

10 MS. ECK: -- I'm sorry --

11 MR. NESBITT: -- this isn't just for
12 people in the room as much as for the court reporter.

13 MS. ECK: Yes. Sorry. So companies
14 should responsibly make the decisions about what's CBI
15 from the get-go understanding that at any point --
16 has always been -- this is nothing new to be honest
17 with you. It's just that we're seeing a trend for
18 request for petitions before they're being posted for
19 public comment. I can't advise you. You all need to
20 make the decision.

21 MS. COATS: Yes. Oh, I understand --

22 MS. ECK: But I can -- between Tonya and

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

134

1 we both can tell you what typically is considered CBI
2 or isn't CBI. So to take a more conservative approach
3 or however you want to look at this and try to
4 more than you used to, that won't fly either because
5 then through the submitter process issues, they're
6 going to come back and say that (indiscernible)
7 withheld in the past. Even if you look at current
8 law -- Tonya can speak to this -- to see what is or
9 isn't CBI.

10 MS. WOODS: She's right. So what happens
11 when we get a FOIA requester and if we made a
12 determination without doing a submitter notice and the
13 requester sued it, we will have to end up doing the
14 submitter notice anyway in the context of any FOIA
15 litigation. Usually, the court will send it back and
16 say, "You didn't hear their views, and so you couldn't
17 -- the Agency couldn't really make a real
18 on what's proprietary to some company." We really
19 actually don't know, which is why we ask, ask you all.
20 Any other questions?

21 MR. NESBITT: Other questions?

22 MS. FITZPATRICK: Just to follow on

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

135

1 that, should we anticipate that 13 out of 20 pending
2 petitions will be on your Web site in a month or a
3 year?

4 MS. WOODS: Well, we're actually -- we
5 last quarter, so they are a few more. We're actually
6 going to go through the year's worth of cases -- only
7 FY'10 cases that we closed, and we're going to make
8 sure that we have posted up all of them. I think
9 maybe eight or nine up there as of this morning. I do
10 apologize, so we've been going through the review of
11 those and making sure that they are appropriate to be
12 put up. Like I said, they've all gone back to you in
13 redacted copies depending on which companies are
14 impacted by the FOIA request.

15 MS. ECK: Tonya, if I could just -- I
16 to clarify here.

17 MR. NESBITT: (inaudible).

18 MS. ECK: Sorry. So those 13 out of 20
19 most of them are 2009 petitions that have been
20 requested, but Tonya's only posting --

21 MS. WOODS: 2000- --

22 MS. ECK: -- (inaudible) --

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

136

1 MS. WOODS: -- 2010 --

2 MS. ECK: -- 2010 --

3 MS. WOODS: -- uh-huh -- requests.

4 MS. ECK: -- so although the 13 out of 20
5 has been requested prior to them been published on our
6 petition table, that's not what, I think -- that's not
7 what we're going to --

8 MS. WOODS: No --

9 MS. ECK: -- be saying, but we're going
10 see if a petition came in in 2010 and a request came
11 for it in 2010 then that petition will be published on
12 our eFOIA Reading Room site. Does that clarify?

13 MR. GILBERT: (inaudible).

14 MS. ECK: Okay. I can't tell you
15 (inaudible) ahead --

16 MR. GILBERT: No, that's --

17 MS. ECK: -- how many --

18 MR. GILBERT: So just to clarify, if
19 was in fact a request -- so it was old request, but it
20 was for a petition which was submitted in 2009, it
21 won't go up and be posted on the eFOIA Reading Room?

22 MS. WOODS: No. Well, we started with --

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

137

1 sorry -- we started with 2010 request --

2 MR. GILBERT: A request made in 2010?

3 MS. WOODS: A request made in 2010,

4 FEMALE SPEAKER: A petition.

5

6 MS. WOODS: -- yes, and it will be
7 whatever -- whatever was asked for in 2010 is what
8 we will post up --

9 FEMALE SPEAKER: Right. Right. Right.
10 Okay.

11 FEMALE SPEAKER: So it could be a
12 (inaudible)?

13 MR. NESBITT: Okay. Other questions?

14 MS. WOODS: It could be (inaudible).

15 MR. NESBITT: We got one here.

16 MR. DAN JACOBS: I'm Dan Jacobs (ph) for
17 Monsanto. Just curious, you mentioned hot topics as
18 being sort of one of the factor to consider --

19 MS. WOODS: Yes.

20 MR. JACOBS: -- including in the reading
21 room. So from an efficiency standpoint the only one
22 that goes then that achieved by using that as a

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

138

1 criteria is that if you're getting multiple requests
2 for single petition, you would put that out there. So
3 would you put each one of those requests for that
4 relatively, maybe even entirely same, information or
5 just put it once? How do you deal with that on the
6 site? I'm just curious. Do you list every single
7 request and corresponding information for that same
8 petition?

9 MS. WOODS: Right. Well, there's two
10 different things. One, APHIS, the FOIA office, has
11 made a determination that for 2010 forward we're going
12 to post full requests 2010 and forward. We're going
13 post the response, the request, and the documents.
14 documents in and of itself that we determine are
15 frequently requested we will post absent a FOIA
16 request. So we've made a determination that we were
17 going to do both, and it's required by the statute.

18 So there's two sort of different things. We
19 can determine -- the Agency can determine, say, we've
20 had some BRS litigation, and we've had multiple --
21 well, we didn't even have to have a request, but we
22 anticipate that we're going to have multiple request

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

139

1 for it, and we're going to say, "Oh, we're just going
2 to -- we got one FOIA request, and we're going to
3 review it, and then we're just going to post it up on
4 the Web, and that's to circumvent other requests from
5 coming in. That's one issue.

6 The other is we have made a determination
7 that we're going to post the responses to FOIA
8 regardless, and so there's two sort of different --
9 it's sort of weird, but it's two different issues
10 happening. Okay. I (inaudible) clear.

11 MR. JACOBS: (inaudible).

12 MS. WOODS: Okay.

13 MS. FITZPATRICK: A question, just a
14 clarification. If a submitter requests existing
15 documents that are in your files, can they also with
16 that bundle in -- and during the next two year if you
17 receive information --

18 MS. WOODS: No.

19 MS. FITZPATRICK: -- they can't go
20 forward?

21 MS. WOODS: No. It has to be -- there's
22 search cutoff that is not -- it's not in our

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

140

1 regulation, but there's a search cutoff that happened
2 through litigation. It's the day we go to search for
3 the responsive records that the search cutoff.

4 MR. GILBERT: It sounds like there's been
5 quite a few policy decisions that have made recently
6 with regarding BRS documentation. I think it would be
7 really helpful to have those policies determinations
8 available for people to know what those determinations
9 are and what those decisions are because I think right
10 now from what the answer I don't think -- it's not
11 transparent with regard to what those polices
12 specifically are.

13 So I think there have been specific
14 made within the Agency with regard to the handling of
15 documents. I think it would be very helpful to sort
16 know specifically in writing what those are.

17 MS. WOODS: Okay. We actually -- we
18 didn't write a policy, and we're governed by the
19 Agency's regulations which should encompass these new
20 amendments to the FOIA that had been a couple of year
21 ago and they're just now being implemented. That's at
22 the Agency level, so we don't have like a formal

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

141

1 in terms of how we're supposed to deal with the
2 records.

3 As far as hot topics, for those concerns,
4 that's an old amendment, and that is in the
5 regulations. So we were always sort of mandated to
6 look at what kinds of records are popular and to put
7 those on the Web so people did not have to come and
8 for another FOIA and contribute to what we had a FOIA
9 backlog at the time.

10 MALE SPEAKER: Just if I could
11 up on Ray's comment. But in terms of transparency,
12 when I look at the words for describing something
13 "Well, we can put something out there that we
14 anticipate we may get requests for" --

15 MS. WOODS: Uh-huh.

16 MALE SPEAKER: -- (inaudible), and
17 there's not a lot of transparency there with how
18 dealing with that very broad language.

19 MS. WOODS: Well, the President even made
20 it more broader, and what we anticipate was what was
21 frequently -- what we think is going to be frequently
22 requested. Now he's made it broader that we don't

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

142

1 want a FOIA for it. And so it's gone from at least
2 we'll get a FOIA request or two, and then we was like
3 "Gosh, we think people are interested in it." Now
4 to the point that he doesn't even want us to have a
5 FOIA request. We want to just give information,
6 involve the public in the process.

7 MALE SPEAKER: But to the point that
8 Anastazia put up there about one of the purposes here
9 of having some of the exemptions so that parties will
10 be willing to share accurate, complete information.
11 And what you're describing it gets broader and have a
12 chilling effect. And so -- and how do you (inaudible)
13 transparency about how you're going deal with the
14 (inaudible)?

15 MS. WOODS: Well, I think -- I guess I
16 thinking that when you have the submitter process I
17 would think that what may be chilling would be having
18 your propriety information out there, having people
19 know like maybe what you're working on, what you're
20 doing. We ask you to review these records before hand
21 before --

22 MALE SPEAKER: And when we do that

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

143

1 even when don't have a FOIA request, when you
2 anticipate that you may get request, will you do that
3 as well?

4 MS. WOODS: Yes, we will.

5 MALE SPEAKER: Okay.

6 MS. WOODS: Like is said, I will not post
7 up any BRS record or submitter -- or any of your
8 records before asking the business submitter what is
9 proprietary, what will cause you propriety harm? We
10 just don't do that.

11 MALE SPEAKER: Okay. Thank you.

12 MS. ECK: Just to -- Tonya, I wanted to
13 add a little clarification because you have talked
14 about the different FOIAs that are out there --

15 MS. WOODS: Okay.

16 MS. ECK: -- and somebody else over here
17 had asked about the policy being established. The
18 truth is BRS is really trying to do some catch-up and
19 be proactive with our transparency, and if you have a
20 chance to look at the APHIS's eFOIA Web site, you'll
21 see that similar type documents across the Agency are
22 already up there. And Tonya does have -- you did put

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

144

1 out a stakeholder notice -- maybe you could speak to
2 that -- about -- these are -- when she's talking about
3 these documents and the way we do things, she's not
4 just talking about BRS. She's talking about all of
5 agencies response --

6 MS. WOODS: Yes. We've going to do a
7 stakeholder announcement that posted to Web site.
8 an alert post that we were planning to post the FOIAs,
9 the responses, and the responsive documents. Those
10 were put up, and we distributed it to the individual
11 program offices beforehand.

12 MR. NESBITT: Other questions?

13 MS. WOODS: Anastazia is going to show
14 the updated BRS Web site.

15 (Pause)

16 MS. TAYLOR: It's FOIA Web site.

17 MS. WOODS: I'm sorry. It's sorry. It's
18 FOIA Web site, the BRS section of the FOIA Web site.

19 MS. TAYLOR: Okay. One second. As
20 showed you the snapshot before, you can see the bottom
21 of the page, but what we've done is we've come to the
22 APHIS's FOIA -- we've come to APHIS Web site itself,

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

145

1 and if you go down to the bottom, there's a radio
2 button that says "FOIA." You click on that button,
3 it brings you to the FOIA Web page itself, and this is
4 what was in the snapshot before showing you the
5 information.

6 You come over here to the right side, and
7 click on "eFOIA Reading Room," and it now brings you
8 the reading room. And this part of the reading room
9 where our programs post what they consider information
10 that may be informative to the public. And midway in
11 the page, you see where it says "eFOIA Requests."
12 These are the electronic FOIA requests that we've
13 posted to the Web page. You choose your year, and
14 right now we just have 2010, and it brings you to a
15 listing of all the programs that have requests that
16 have been made and posted. Choose "BRS," and these
17 the documents that have been posted for BRS to our Web
18 page. I'm going to choose the first one, and as you
19 see, as listed here, we have a FOIA request, the
20 response letter, and the responsive record themselves.
21 And these are the responsive records as redacted and
22 given to the FOIA requester.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

146

1 (Pause)

2 MS. TAYLOR: Is there anything else
3 you wanted to say?

4 MR. NESBITT: Any further questions?

5 MS. COATS: Could we see one of the logs
6 where you say --

7 MR. NESBITT: What --

8 MS. COATS: -- FOIA -- the FOIA log?

9 MS. TAYLOR: Yes.

10 (Pause)

11 MS. TAYLOR: I don't know how
12 (inaudible).

13 MS. WOODS: Is it -- is one in there?

14 MS. TAYLOR: Yes.

15 (Pause)

16 MS. WOODS: Did you want to see the
17 or the --

18 MR. GILBERT: Yes, the record.

19 MS. COATS: Yes.

20 (Pause)

21 MS. TAYLOR: This a FOIA log.

22 MS. COATS: Now are these complete?

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

147

1 MS. WOODS: It depends on what they ask
2 for. So say we had one who asked -- I mean I -- we
3 recently had - - I'm sorry -- we recently had a
4 for the BRS FOIA log. We've had them for the entirety
5 of the FOIA log. We get them from the media, from
6 whomever, and so it depends on what snapshot they're
7 looking for. So if they ask for the complete FOIA log,
8 we're here, that's what we'll provide minus any
9 sort of information thing like -- it might be some
10 information that we withhold out it.

11 MS. COATS: But every requested would be
12 listed?

13 MS. WOODS: Yes.

14 MS. COATS: Okay.

15 MS. WOODS: And before we release.

16 (Pause)

17 MR. NESBITT: Questions?

18 (Pause)

19 MR. NESBITT: Okay. Then I think we will
20 transition to our next section. Thank you very much
21 ladies, both of you.

22 (Pause)

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

148

1 MS. WOODS: Thank you.

2 MS. TAYLOR: Thank you.

3 (Pause)

4 MR. NESBITT: Give us just a moment for
5 to set up this next presentation. Lee, I think you're
6 up next.

7 (Pause)

8 MR. NESBITT: We're running just a little
9 bit ahead in the schedule, so we're skipping past
10 to the next speaker, and then we'll take a break after
11 that.

12 (Pause)

13 MR. LEE HANDLEY: Hello, everyone.
14 If you don't know who I am, I'm Lee Handley. I'm a
15 Senior Biotech in the risk assessment program, and I'm
16 also the liaison between BRS and the contractor who
17 works on ePermits. I just want to give a really brief
18 update on where we are with some of the changes and
19 things that we're doing with ePermits. Do I control
20 that?

21 FEMALE SPEAKER: Oh.

22 MR. HANDLEY: Okay.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

149

1 (Laughter)

2 MR. HANDLEY: As many of you know, we're
3 in the process of developing an online reporting
4 for ePermits where you'll be able to submit your
5 planting reports, volunteer monitoring reports, final
6 field test report through ePermits electronically.
7 Right now everyone submits your permits and
8 notifications through ePermits, and that's all handled
9 electronically, but everyone's still sending in all
10 their other reports by paper. So what we're doing is
11 we're building a module that will let you submit all
12 that electronically. We had hoped to have that, well,
13 in early fall. We had an initial testing period, and
14 we found some glitches in the system, and also
15 we decided we wanted to add a couple of more
16 enhancements at the time, so the projection now is
17 we should be able to launch in January.

18 And I know a lot of you like to do all your
19 submissions using XML uploads. We're going to offer
20 the ability to upload the reports through XML, and of
21 course, you also need the ability to test your
22 And I know some of you have used the testing site that

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

150

1 we have for permitting and notifications. We're going
2 to have that same site available for testing your
3 uploads of the reporting module.

4 It's going to be a little bit more
5 complicated than we've done in the past because in the
6 past you could just upload a permit and check to make
7 that the schema was correct. At this point, you'll
8 have to have -- you'll have to upload a permit, a fake
9 permit, and then you'll need to upload your fake
10 planting reports, field test reports, and that kind of
11 thing. You can also remember don't ever submit a fake
12 permit, notification, report that has CBI in it. It
13 needs to be completely made up because this is not --
14 the test site is not a secure site unless the
15 production site, which is a secure site.

16 So the other thing is that the online
17 reporting is probably going to be a lot more
18 complicated than we've had with permitting and
19 notification, so we're developing like a help
20 documentation for the module. I know a number of you
21 have asked for the data elements that will be in the
22 reporting module, and I've sent those out. If other

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

151

1 people want to see -- that haven't see that, what
2 data elements are, I'll be glad to send them to you.
3 Just contact me and I'll send them. We will post that
4 on the ePermits Web site once it's finalized. The
5 schema will be there and all the other documentation
6 you need.

7 Also with the reporting module, like we have
8 in the permitting side of things, in certain places
9 where there are field that you might have questions
10 about, there will be a link where you can click on an
11 explain button, and it will pop up information that
12 tells you what we're looking for there. But that will
13 also be in the documentation that we send out as well.

14 So as I said, we hope to launch in January,
15 and the same day we'll launch the -- we will have the
16 testing site available. Most of you already have user
17 names for the test site, but if you don't, contact me,
18 and we can get you set up for that. Right now it's
19 available because it's not functional, but once we
20 it up and running, all those user names will be
21 activated. So I think that's pretty much it. Any
22 questions?

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

152

1 (Pause)

2 MR. HANDLEY: Yes.

3 MR. NESBITT: All right. We'll switch
4 (inaudible) it's hard to turn on.

5 (Laughter)

6 MS. BUEHNER: I just have a question
7 about the XML uploads to the schema. Is that when the
8 schema will be available for that or will we have that
9 (inaudible) --

10 MR. HANDLEY: As soon as it's ready,
11 send it out ahead of time.

12 MS. BUEHNER: Okay.

13 MR. HANDLEY: I know that you guys really
14 need that, but because we're still tweaking some of
15 elements, we don't want to send it out now and then
16 have to correct it a week later.

17 MS. BUEHNER: Correct.

18 MR. HANDLEY: So as soon as -- as soon as
19 the contractor says, "Yes, it's locked down, it's
20 to go," I'll send I out, and it will be posted on the
21 Web site. There's a separate Web site that has all
22 schema information for permits and notifications.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

153

1 It'll also have the schema information for all the
2 reporting modules.

3 MS. BUEHNER: Okay. Thank you.

4 MR. NESBITT: Other question? Upfront.

5 MALE SPEAKER: So you mentioned at
6 one point that putting some other functionality in
7 there. One thing we were hoping for was the applicant
8 not only being the only person to have that access,
9 you have multiple -- or one person could do multiple
10 notifications even though they (inaudible) the
11 application.

12 MR. HANDLEY: Right. Right.

13 MALE SPEAKER: Curious if that's in
14 there yet?

15 MR. HANDLEY: We're working on it. We
16 call it the organizational applicant so that -- the
17 problem is that you have -- only one person can be e-
18 authenticated. And so that person who is e-
19 authenticated also is the owner of the permit and the
20 notification, which by default is also going to be the
21 person that has to upload the reports -- planting
22 reports and all that for that one notification or

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

154

1 (inaudible).

2 What we're working on is a way that once you
3 log in through e-authentication then there's another
4 gateway that you would go into that says "I am a
5 of company X; therefore, I can see all of the permits,
6 all of the notifications, and all the reports for my
7 company or my organization, so we're in the process of
8 designing that and working on it. Right now, the
9 budget situation since we're under a CR -- we
10 have the design done. We just need to get the money
11 finish it, so that's kind of where we are.

12 MR. NESBITT: Any other questions? Yes.

13 MS. COATS: What you mentioned was that
14 you've got that organizational applicant concept
15 finished would that allow people from one company to
16 see everything that they submitted? How about
17 submitting reports even if you're not the notification
18 holder --

19 MR. HANDLEY: This --

20 MS. COATS: -- without --

21 MR. HANDLEY: -- that's how it was
22 designed to work. So if you have one employee that

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

155

1 submitted a permit, a whole another group may submit
2 reports, that person would be able to go and say "I
3 want to submit the report for this permit even though
4 didn't submit it.

5 MS. COATS: Okay.

6 MR. HANDLEY: It would also let all
7 within an organization share each other's permits and
8 notification so if one person starts working on it and
9 another person needs to finish if they could.

10 Also we've had a situation where a person
11 will leave a company. We have to go in and manually
12 reassign those back to another employee in the company
13 so that they can see them again. The whole problem is
14 really the fact that e-authentication doesn't allow
15 corporate accounts, so we're having to go beyond e-
16 authentication to the next level to let people share
17 things.

18 MS. COATS: Thank you. I think that
19 be helpful to --

20 MR. HANDLEY: Yes.

21 MS. COATS: -- all of us, and in light of
22 possibly having to submit things faster than we've had

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

156

1 to in the past, well, that's not been decided, that
2 little bit would help just on the procedural side.

3 MR. HANDLEY: Sure.

4 MS. FITZPATRICK: What you said
5 sort of having everyone in the company being able to
6 see all permits is there a way that the permit
7 applicant could assign responsibilities for just
8 reporting what we're -- but not the final report. Is
9 there a way to fill in that somewhat more narrowly?

10 MR. HANDLEY: That we haven't got in the
11 design. What -- there will be like an administrator
12 for each organization, say, the head of compliance or
13 whoever that -- that person that dictates who will be
14 allowed in the company or organization to see each
15 other's things. In other words, you guys will control
16 who has access, not us. So you can invite different
17 people in your organization to join the company or the
18 applicant's organization, but we don't have it set up
19 that they can only do certain tasks. They would be
20 up to do all the tasks within the ePermits system.

21 MS. FITZPATRICK: The second
22 was the January 2010 launch could you explain that in

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

157

1 more detail if that's a forward-looking launch or is
2 that from that day forward things will have to change?

3 MR. HANDLEY: It will be available in
4 January for uploading, but that doesn't mean that you
5 immediately have to start using it. The other thing
6 that -- and I think everybody's doing this now -- is
7 your applications the only way you're going to be able
8 to upload into the reporting module is if you use
9 location- unique IDs because what's going to happen is
10 that if you're trying to upload planting reports and
11 field test report it's going to have to look for a
12 location to know where those planting reports go or
13 field test and that kind of thing.

14 We implemented that requirement I guess it
15 was about -- it was in August, so if you submitted any
16 kind of application since August, you will have had to
17 use that organizational ID so it will work; you'll be
18 able to upload your reports. Anything prior to that
19 that won't.

20 The one place where we're going to
21 potentially have to be on the lookout is for multiyear
22 permits, like 3-year permits for grain yields. Those

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

158

1 we'll have to make sure -- you won't be able to upload
2 unless you've got a unique ID in there. You can do --
3 submit manually, but you won't be able to use the
4 uploading process.

5 We know who you are, the multiple permit
6 holders, so we'll be able to let you know when the
7 comes whether or not you'll be able to upload. It's
8 just a matter of adding a unique ID to the location.

9 MR. NESBITT: Other questions for Lee?

10 (Pause)

11 MR. NESBITT: Yes.

12 MR. BOTTOMS: With the corporate accounts
13 that you mentioned, will this impact BRS permits as
14 well as PPQ permits based on (inaudible).

15 MR. HANDLEY: This has been -- that's an
16 interesting question. There are different parts of
17 APHIS who see the advantage of this and other parts
18 don't, but we're designing it so that any program in
19 APHIS could you it. So that if other programs decided
20 they want to have an organizational applicant as a
21 of their permitting process, it will be built to work
22 in all of the parts of ePermits because it's right

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

159

1 after you log in. You aren't in BRS or vet services
2 PPQ. You can - - they will be available, but the
3 program has to allow it.

4 MR. NESBITT: Anything else?

5 (Pause)

6 MR. NESBITT: Going once? Okay. Thank
7 you, Lee.

8 MR. HANDLEY: Sure.

9 MR. NESBITT: I think at this time we
10 take a 15-minute break before our next speaker comes
11 in, so we will resume, shall we say, right before 3
12 o'clock. Thank you.

13 (Off the record) (On the record)

14 MR. NESBITT: Our first speaker now after
15 the break and our last official speaker for the day is
16 Tom Sim, our, sadly, soon-to-be former division
17 director of the Regulatory Operations Program here in
18 BRS. Tom is going to give us an update on where we
19 with BQMS. Thank you, Tom.

20 MR. TOM SIM: Thanks, Clint. And despite
21 the rumors you heard this morning that I requested to
22 me, those are only false.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

160

1 (Laughter)

2 MR. SIM: Many of you who were here last
3 year heard Dr. Jhee give an update on the BQMS sort of
4 the background of the program, so I'm just going to
5 to pinch hit for him today. They're out on the West
6 Coast helping some of our newer participants, so don't
7 ask me any tough questions. I'm not sure I'll be able
8 to answer them, but since we had that discussion last
9 year, I'm just going to focus mostly on things that
10 have happened in 2010. But before I do that, for
11 of you who weren't here last year, just let me, if
12 you'll indulge me, give me a few moments to talk about
13 background.

14 I'm going to go back to 2004 when BRS
15 installed its compliance function, and the two major
16 efforts at that time were inspection and compliance
17 evaluation and enforcement. And when I got here in
18 2005, we did kind of an analysis of some of the
19 infractions that we had seen over the years, and it
20 interesting to note that many of them were decisions
21 that were made during the conduct of a trial that
22 actually lead someone to go down a path toward

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

161

1 noncompliance. So we figured, "Well, how can we stop
2 that or minimize that, and we'd really like to get
3 folks on a path to being in compliance and staying
4 there."

5 So we did a little more analysis and tried
6 -- and a compliance-assistance function was the idea
7 that we came up with to help people in the regulated
8 community achieve and maintain compliance by making
9 intelligent decisions as they conducted the field
10 trials. So this assistance effort was designed to
11 complement both the inspection and the enforcement
12 functions of the program.

13 The approach we took was to employ
14 of quality management, which had been used both in
15 government and the private sector for many years. The
16 BQMS was drafted during 2006 from 2007, and the
17 Department announced the program in 2007. In 2008, we
18 got ourselves ready to conduct the pilot; and in 2009,
19 we kicked that off with five participants who
20 volunteered to help go through the program for the
21 first time.

22 Following the pilot, we did an analysis of

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

162

1 the program. So, Colleen, if you could go to the next
2 slide please. Of course, we have to have a mission
3 goal statement. But this is the statement that our
4 analysis and review team came up with, and there's a
5 lot of key words in that sentence. I'll just read it:
6 "To provide support for the voluntary adoption of a
7 BQMS to improve the management of an organization's
8 domestic research and development of regulated GE
9 organisms."

10 So those few words really says a lot about
11 the program. First of all, it's voluntary. An
12 organization can decide whether or not they wish to
13 participate in the audit portion of the program.
14 Again, it's designed to improve the management of
15 domestic -- not any international implications at all
16 -- domestic research and development, not commercial,
17 of regulated -- only those regulated -- GE organisms.
18 So there's a lot in that mission statement.

19 A couple of goals we came up with were --
20 they're on the screen -- just to provide clarity and
21 expectations of the responsibilities and to provide
22 compliance assistance to the regulated community for

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

163

1 the regulations.

2 Some of the thing I'll visit with you about,
3 as I said, the pilot project was concluded in 2009.
4 immediately started an evaluation of that effort. We
5 included comments from the participants who gave us a
6 lot of good feedback based on their -- we all learned
7 lot together through that, so that was very useful.
8 had solicited comments on the draft audit standard in
9 the Federal Register notice during 2009. Of course,
10 those comments were evaluated. We also have a group
11 here in APHIS called Program and Policy Development,
12 which helps programs do analysis, and they led us
13 through a number of exercises to help evaluate the
14 program.

15 Some of the things that were developed are
16 listed there under that last arrow bullet. The draft
17 audit standard was published last summer, and it
18 contains the expectations of the audit points of the
19 program. The checklists that are listed there each
20 of those addresses an audit point within the standard,
21 and we're using an inquiry-based approach. There's a
22 number of questions for each check point that leads

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

164

1 participant to making the right -- defining their
2 process in the right way that'll be compliant with the
3 regs. And the guidelines listed there address the
4 audit's expectations.

5 So the development tools we've listed are
6 templates the participants can use for developing
7 procedures. And the last item there, the operational
8 procedures, these are the ones that we use internally
9 within BRS when reviewing audit report and that sort
10 thing. All these documents are available on the Web
11 site, and you don't have to be an audit participant to
12 make use of any of these documents, so if any of them
13 are useful to you, feel free to check them out and use
14 them if you think they'll be useful.

15 We did have a Federal Register in July
16 soliciting participants for the next class, which
17 in late September. And like I said, some of those
18 staff are out on the West Coast now working with some
19 of those -- the newer participants. We've got two
20 classes planned for 2011: One's in February, which is
21 full; and there's one in August; I think there may be
22 two or three slots left for that one. We're going to

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

165

1 utilize an open- enrollment approach. If you're
2 interested, contact Dr. Jhee and let him know if
3 interested, and we'll try to work you into the class.
4 We're taking into consideration the interest of the
5 organization, where their geographic location is so we
6 can try to consolidate and make these efficient as
7 possible for everyone involved.

8 And I think there is one more slide. Like I
9 said, all those documents are located on the Web site
10 and some under the compliance portion of our Web site;
11 it's under the "News and Information," so be sure and
12 hit the "News and Information" button if you want to
13 look at any of these documents. That's just a quick
14 overview of what happened this past year.

15 I might also mention that we've been working
16 with the Excellent Through Stewardship folks this past
17 year to maybe harmonize some of the claims that are in
18 common and minimize their -- everyone's -- both
19 participants' -- both programs as we do -- we're
20 to set up concurrent audits and that sort of thing, so
21 that's been a very useful exercise too. And we
22 appreciate that very much.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

166

1 MR. NESBITT: Do we have any questions
2 from the floor for Tom?

3 (Pause)

4 MR. NESBITT: Everybody's getting sleepy.

5 (Laughter)

6 MR. NESBITT: Okay, Tom, I think you're
7 off the hook then.

8 MR. SIM: Okay. Thanks.

9 MR. NESBITT: Thank you.

10 (Applause)

11 MR. NESBITT: Sid, would you like to come
12 to the front and join Bev in a Q-and-A session?

13 (Laughter)

14 MS. BEVERLY SIMMONS: (inaudible)

15 (Laughter)

16 MS. SIMMONS: Well, I want to thank
17 everybody for taking time out of a busy day to come
18 spend it in Riverdale. I know this isn't always the
19 easiest place to get to. We welcome the opportunity
20 least in the annual stakeholders meeting to have a
21 chance to share information with you and also learn
22 from you areas where, hopefully, we can improve our

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

167

1 processes and serve your interest better.

2 Mike said this morning that 2010 has been an
3 eventful year for us. That could be an
4 but I think the expectation is that we see for at
5 the next months ahead that we're going to have some
6 challenges, but we also are going to have to be
7 creative and, hopefully, effective and efficient in
8 making sure that our program delivers what it needs to
9 both for you and for the American public.

10 I don't know -- this morning Mike had
11 the opportunity to pick his brain and provide you any
12 information on responses to questions you might have.
13 I don't know if you've thought about anymore during
14 course of the day or if any of the conversations,
15 sidebars that you've had maybe have prompted some
16 questions that you might want to raise -- you get two
17 new faces here, and we'll try to respond if you do
18 anything that you would like us to respond to. So
19 kind of open it up.

20 MR. NESBITT: Do you have any questions
21 for Bev and/or Sid? Does everyone know Bev and Sid?
22 Should you two want to introduce yourself?

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

168

1 MS. SIMMONS: This is Bev. That's Sid.

2 (Laughter)

3 MR. NESBITT: That's -- (Laughter)

4 MR. NESBITT: Fair enough.

5 (Laughter)

6 MR. NESBITT: Questions from the floor?

7 MR. GILBERT: I didn't hear -- Mike
8 I don't think alluded to any future attempts to revive
9 the revisions to part 340 regulations. Just wanted to
10 know if on tap for 2011 what's any current status or
11 any thoughts on future progress on going back to try
12 and revise the regulations?

13 MS. SIMMONS: He mentioned this morning
14 some issues and topics that are being discussed more
15 broadly in the Department, and certainly in the
16 of those broader discussions, the topic of 340 does
17 come up from time to time as to whether or not there
18 I guess reason or rationale to look at these issues in
19 the context of what we had proposed for 340 and
20 or not there's a need to go back to seeing where we
21 want to take those revisions.

22 So while there's not a formal plan as to

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

169

1 that might proceed, certainly it is continuing to be a
2 topic of discussion, so I don't want you to think that
3 people have just said "Okay, we're just ignoring 340,"
4 but it certainly is being talked about in the context
5 of these other issues.

6 MR. ROGAN: You mentioned that BRS had
7 increased their NEPA resources has OGC also increased
8 their resources, and is that going to be the
9 bottleneck?

10 MS. SIMMONS: It's interesting you raised
11 that because certainly our colleagues in OGC -- and
12 actually they're not here today, and they normally do
13 attempt to come and attend these sessions so they can
14 get a sense of sort of what the issues are that our
15 stakeholders have. I think one of the reasons they're
16 not here today is because they are, as you're well
17 aware, under a great deal of pressure to get a number
18 of issues resolved.

19 Certainly, the topic of how we help them
20 effectively use our resources is something that is
21 being discussed. Whether or not in the budget climate
22 we're in that means actually additional bodies, I'm

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

170

1 really sure that that's probably very realistic. But
2 certainly I think there are ways that we can be
3 with them about how do we work smarter with them to
4 help them do the work that they need to do and
5 represent us. So it certainly is a topic we have been
6 discussing.

7 MR. NESBITT: Other questions from the
8 floor?

9 MS. FITZPATRICK: I had a question.
10 There was a brief mention that Michael Gregoire had
11 mentioned regarding revising SOPs as to timing and
12 changing some steps. I thought you just said in the
13 permitting process and how the internal review works.
14 Other than that I was discussing with thought it might be
15 petitioning process. Could you clarify?

16 MS. SIMMONS: Yes. As I recall, this
17 morning he was referring to the petition process, and
18 he did mention that we are availing ourselves of some
19 techniques with respect to Lean Six Sigma, which some
20 of you may or may not know that that is something that
21 the Secretary feels very, very strongly about -- Ahh,
22 there's Mike -- because when he was governor that was

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

171

1 used in a number of areas to try to bring process
2 improvement in the state of Iowa, so the mention this
3 morning was in the context of the petition process.

4 Okay, Mike.

5 (Laughter)

6 MR. GREGOIRE: You're doing great.

7 MS. SIMMONS: Oh, good.

8 (Laughter)

9 MS. SIMMONS: That's good to know.

10 MR. GILBERT: Maybe can you just
11 with regard to if there are specific timelines on
12 moving through that process?

13 MS. SIMMONS: Specific timelines. We
14 a plan -- and where is Clint. Clint is in here
15 somewhere Clint is our champion for this project, but
16 he's also working in collaboration with others in
17 APHIS. I don't think that we have publicly outlined
18 the timeframes that we'll be using to move this
19 forward. Certainly, it's got very high priority, so
20 we're talking about timelines that are sooner rather
21 than later, so you should be seeing some movement in
22 this area in the next months.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

172

1 MR. NESBITT: Any other questions? Mike,
2 would you like to make a comment or shall we refer all
3 questions to you?

4 MR. GREGOIRE: Well, if folks have
5 additional questions, I can help answer those.

6 MR. NESBITT: Question for the...

7 (Pause)

8 MR. NESBITT: Okay. Then there are no
9 question (inaudible).

10 MS. SIMMONS: Could I remind everybody
11 please that before you leave if you would mind filling
12 out the evaluation forms. It is always helpful for us
13 to kind of know what worked and what didn't work, what
14 areas you would like us to focus on in the future
15 meetings.

16 I was kind of surprised when we put the
17 announcement out for this meeting we did ask whether
18 not there was any input that stakeholder wanted to
19 provide as to how we might direct the agenda, and I
20 kind of surprised because I don't think you guys are
21 kind of a shy type that we didn't get feedback with
22 respect to that.

Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

173

1 So we certainly want to encourage you if
2 there are ideas that you have or areas that you want
3 to focus on in future engagements we certainly would
4 appreciate getting that information.

5 MR. NESBITT: Okay, that's it.

6 MS. SIMMONS: Other than that, thank you
7 very much. See you next year.

8 (Applause)

9 (Whereupon, the Biotechnology
10 Services Public Stakeholder Meeting
11 was concluded.)

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Capital Reporting Company
Biotechnology Regulatory Services Meeting 12-01-2010

174

1 CERTIFICATE OF COURT REPORTER

2

3 I, JEFFREY MICKLE, the officer before whom the
4 foregoing meeting was taken, do hereby certify that
5 testimony of said witness was taken by me in stenotype
6 and thereafter reduced to typewriting under my
7 direction; that said deposition is a true record of
8 testimony given by said witness; that I am neither
9 counsel for, related to, nor employed by any of the
10 parties to the action in which this deposition was
11 taken; and, further, that I am not a relative or
12 employee of any counsel or attorney employed by the
13 parties hereto, nor financially or otherwise
14 in the outcome of this action.

15

16

17

18

Jeffrey Mickle

19

Electronic Court Reporter

20

21

22

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 1

<u> </u> \$	<u> </u> 2	<u>27</u> 23:12	<u> </u> 8
\$10 4:14	2 28:20 90:2 93:21	<u> </u> 3	8 36:22 114:3
\$13 24:9	97:7 104:18	3 94:7 97:7,20	800 26:10
\$19 24:10	112:21	113:3 159:11	89 2:18
<u> </u> 1	2,068 25:14	33 2:8 116:8	<u> </u> 9
1 1:13 28:11 42:7	20 26:2 87:17	120:14 121:3	9 114:8
87:13 97:7	88:11 132:9	340 168:9,16,19	900 37:1
104:18 112:18	135:1,18 136:4	169:3	<u> </u> A
1,000 36:21	2000 34:1 37:20	38 2:10	abandoned 106:15
1:45 110:17	135:21	391 83:5	Abel 12:14
10 22:21 26:1	2004 160:14	3-year 157:22	ability 149:20,21
127:13	2005 27:19 36:16	<u> </u> 4	able 22:17 23:22
11 17:4,8,12 30:10	37:4 160:18	4 2:2 113:6	25:7 49:16 52:8
11:00 4:13 75:18	2006 161:16	118:5,15 119:5	73:10 87:5
111 3:2,3	2007 161:16,17	120:9	97:15,20 98:6
12 99:19	2008 161:17	40 41:15	99:8 100:22
12,000 116:11	2009 36:16 135:19	45 15:5	101:18 102:6
12:15 16:10	136:20 161:18	4700 1:11	104:16 149:4,17
12600 120:1	163:3,9	48 116:10	155:2 156:5
13 2:5 132:8,10	2010 1:13 15:3	<u> </u> 5	157:7,18
135:1,18 136:4	22:11 23:5 25:19	5 23:2 75:18 99:14	158:1,3,6,7
14 85:11	83:5 116:7,10	113:11	160:7
146 3:6	117:8,9	500 25:15 26:9	absent 138:15
15 75:10 87:17	120:18,20	<u> </u> 6	absolute 112:16
1501.1(c) 46:5	136:1,2,10,11	6 28:19 32:13	academic 71:21
159 3:10	137:1,2,3,7	6,000 36:17	72:7,11,13
15-minute 75:17	138:11,12	61 2:13	academics 59:9
159:10	145:14 156:22	<u> </u> 7	accept 67:19
166 3:13	160:10 167:2	7 113:16	accepted 126:15
18 20:18 31:13,22	2011 15:3 24:8	70 85:8	accepting 68:16
1954 17:4,8,12	25:9,20 26:1	708 116:8	access 58:12 71:20
1970 42:1	27:1 30:10 68:17	76 2:16	83:3 84:13 116:6
1974 42:17	82:1 164:20		153:8 156:16
1979 47:8,10,13	168:10		accessed 50:4
	2012 28:8		accommodate
	20737 1:12		
	24 23:12		
	244,000 27:11		

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 2

<p>22:1</p> <p>accomplishments 14:12 15:3</p> <p>account 40:4 41:18 42:10 96:17</p> <p>accountabilities 80:12</p> <p>accountability 80:16 95:4 114:12,13</p> <p>accounts 155:15 158:12</p> <p>accurate 79:18 80:21 83:9 118:13 142:10</p> <p>achieve 46:18 161:8</p> <p>achieved 137:22</p> <p>achievement 44:21</p> <p>Achieving 114:14</p> <p>Achor 10:5</p> <p>acquire 118:4</p> <p>acronym 76:10</p> <p>acronyms 98:18</p> <p>across 83:4 143:21</p> <p>Act 2:8 3:3,4 15:21 34:1,3 44:4 111:10,12,18 122:17</p> <p>acted 24:22</p> <p>acting 4:6</p> <p>action 29:6 43:11 48:16 49:3 50:13 51:5,7,9,11 52:3,11,12,14,21 53:9,12 54:9</p>	<p>81:19 174:10,14</p> <p>actions 34:9,14 39:17 43:1,4,5 44:8 46:13,16 48:12,14,17,22 51:18 53:10 54:3,4,7,8 56:2 79:1 81:6</p> <p>activated 151:21</p> <p>activities 19:21 36:5 44:17,21 76:21 77:5 79:1,10 101:1</p> <p>activity 77:6 104:22</p> <p>actual 45:1 92:20 99:1 117:6 123:1,4</p> <p>actually 29:15 39:9 58:1 61:10 70:1,15,22 71:7 73:5 90:15 97:11 98:9,11 100:9 101:8,9 106:14 121:4 122:8,9 123:17 124:15 125:17 126:20 129:13 134:19 135:4,5 140:17 149:14 160:22 169:12,22</p> <p>add 26:19 38:2 73:2 74:13 143:13 149:15</p> <p>added 54:3 55:7</p> <p>adding 158:8</p> <p>additional 20:8 22:19 24:2,4,7,10 32:12 100:4</p>	<p>169:22 172:5</p> <p>additions 24:1</p> <p>address 83:9 90:19 95:8 109:20 117:1 164:3</p> <p>addressed 58:19</p> <p>addresses 163:20</p> <p>adds 31:21</p> <p>adjudication 113:20</p> <p>administration 80:1,3,6 84:12</p> <p>administrative 113:1 115:19</p> <p>administrator 2:6 6:13 7:18 9:11 156:11</p> <p>Administrator's 31:20</p> <p>admittedly 85:9</p> <p>adopted 115:18</p> <p>adoption 162:6</p> <p>advance 48:16 50:6</p> <p>advanced 36:14 41:8 50:4</p> <p>advantage 158:17</p> <p>adverse 42:20 49:14 51:6</p> <p>adversely 119:6</p> <p>adverted 43:3</p> <p>advertisement 61:18</p> <p>advice 113:13</p> <p>advise 118:16 119:3,17 133:19</p>	<p>advised 130:1</p> <p>affect 57:19 130:6</p> <p>affected 54:22 57:6,7,11 58:13 94:14</p> <p>afford 119:7</p> <p>afternoon 3:1 16:13 26:6 31:11 78:15 83:21 111:1,4</p> <p>afterward 6:3</p> <p>against 35:13 42:18</p> <p>agencies 40:2 41:9,20 42:8,12 43:9 45:1,3,6,10,15,2 2 47:3,5,12,15,16 56:1,3 79:11 103:21 112:1,2,15 114:15 118:1 144:5</p> <p>agency 11:16 27:19 28:6,11,15,21 29:12,18 30:5 34:5 35:13 40:7 43:11,19 45:18 49:19 52:3,9 54:5 56:18 60:17 65:18 73:22 74:1,5,18 75:4 77:19 81:1 83:4 111:19 112:11,12,13 113:2 114:6,19 115:17,18 116:8 118:17 119:9,12,16,19</p>
---	--	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 3

120:1 125:22 127:2,4 134:17 138:19 140:14,22 143:21 agency's 27:17 80:11 111:4 114:21 140:19 Agency-specific 81:2 agenda 14:20 15:6 172:19 ago 20:18 47:19,22 74:1 100:12 140:21 agreed-upon 128:6 agreeing 126:21 agreements 64:22 68:10 agricultural 9:13 24:18 56:11,21 57:2 58:16 83:14 agriculture 1:5 41:4 56:21 85:3 AgroSciences 7:5,7,10,12 8:1,12 10:4,6 ahead 4:15 75:10 91:9 123:21 126:1 136:15 148:9 152:11 167:5 Ahh 170:21 aim 44:19 air 49:15 58:20 Akela 11:14 alert 144:8	alfalfa 27:6,9 29:17,18 alive 123:8 alleviate 38:7 allied 96:4 allow 45:21 154:15 155:14 159:3 allowed 156:14 allows 40:10 50:10 112:18,21 113:3,6,11,17 114:3,8 alluded 37:19 168:8 already 26:3 37:11 48:12 55:18 58:2 66:13,19,22 67:8 70:1,19 91:1,14 92:8 106:15 115:4 143:22 151:16 alternative 28:13 45:22 48:7 52:2,11 alternatively 50:11 alternatives 28:3,13 45:17 51:9,17,21 52:7,9,17,20 53:6 57:8 58:2,4,7,10 59:18 60:16 am 148:14 154:4 174:8,11 Amber 7:6 97:3 amendment 141:4 amendments 140:20	America 56:21 American 167:9 among 53:4 amongst 79:10 87:16 amount 45:10 114:20 amounts 55:19 Anabol 11:9 analyses 62:16 65:18 68:10 analysis 2:9 15:22 18:17 20:3,5 21:3,9 29:6 31:18 33:6 36:5 39:12 40:13,17 54:15 62:11 63:9,18 64:3,6,14,17 65:13,20 66:11,19 67:9,12,16 68:5 84:17 160:18 161:5,22 162:4 163:12 analysts 20:4 analytic 58:6 analyzed 28:2 63:16 analyzes 29:20 Anastazia 3:4 111:4,8,9 142:8 144:13 and/or 167:21 and-paste 96:18 Andre 10:12,13 Andy 74:13 animal 1:6 58:20	59:1 Ann 7:2 12:10 ANNIE 7:2 announced 161:17 announcement 144:7 172:17 announcements 4:10 6:6 91:18 103:2 annual 13:17 166:20 answer 3:13 14:15 15:8,10 22:7 83:7 107:6,8 122:7 128:16 140:10 160:8 172:5 answered 82:22 83:5 answering 60:7 answers 16:16 83:9 anticipate 114:18 135:1 138:22 141:14,20 143:2 anticipates 28:6 anymore 167:13 anyone 12:16 68:19 71:10 73:19 74:13 75:12 88:6 131:2 anything 6:4 59:11 121:19 146:2 157:18 159:4 167:18 anyway 125:1 134:14 anywhere 107:9
---	---	--	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 4

<p>APHIS 2:5,19 6:13 9:11 10:11 21:8 23:18 29:10,16 30:18 40:3 41:2 47:18 48:16,20 49:16 50:20 56:20 73:6 77:13,19 79:1 83:22 84:2 85:4 102:14,16 111:6 115:8 116:4,20 117:17 119:11,13,15 120:5 138:10 144:22 158:17,19 163:11 171:17</p> <p>APHIS/BRS 4:3,5 7:14 8:4</p> <p>APHIS's 143:20 144:22</p> <p>apogemid 49:18</p> <p>apologize 38:13 135:10</p> <p>apparently 4:18</p> <p>appeal 32:9</p> <p>appeals 32:10 42:16</p> <p>appears 54:6 100:10</p> <p>Applause 33:2 166:10 173:8</p> <p>applicable 79:11</p> <p>applicant 64:20 65:1 66:17 69:10 71:16 95:14 153:7,16 154:14 156:7 158:20</p> <p>applicant-funded 65:17 67:11</p>	<p>applicant-prepared 65:12</p> <p>applicants 63:19 64:5,16 71:15</p> <p>applicant's 156:18</p> <p>applicant-submitted 67:20</p> <p>application 45:7 67:22 98:10 153:11 157:16</p> <p>applications 87:11 157:7</p> <p>applied 47:12</p> <p>applies 113:8 117:10</p> <p>Applying 103:5</p> <p>appraise 44:16</p> <p>appreciate 13:18 16:7 88:19 110:3 165:22 173:4</p> <p>approach 31:1 134:2 161:13 163:21 165:1</p> <p>approaches 62:16,17</p> <p>appropriate 29:5 135:11</p> <p>Appropriation 24:19</p> <p>appropriations 24:7,18,21</p> <p>approved 133:1</p> <p>approximately 62:5 116:11</p> <p>April 17:4,8,12</p> <p>archival 102:5</p> <p>archives 98:2</p>	<p>Archiving 102:3</p> <p>ardose 70:12</p> <p>area 16:7 25:21 57:7,11,13,19,21 ,22 58:1,22 59:2 95:6,9 99:18,19 106:3 123:7 171:22</p> <p>areas 14:17 15:2,19 27:2 57:15 58:12,20 59:10 166:22 171:1 172:14 173:2</p> <p>aren't 15:13 25:8 73:10 90:17 159:1</p> <p>arrived 110:13</p> <p>arrow 163:16</p> <p>aside 15:8</p> <p>aspects 36:2 108:14</p> <p>assert 57:1</p> <p>assessed 43:11</p> <p>assessing 48:6</p> <p>assessment 3:8 28:12 34:15,22 35:8 40:16 43:16 47:20 50:8 51:1 67:4 68:3 85:18 148:15</p> <p>assessments 36:5 60:3</p> <p>assign 156:7</p> <p>assistance 19:10,17 20:8,9 23:7 161:10 162:22</p> <p>Associate 7:18</p>	<p>9:11</p> <p>associated 49:2,5 70:18</p> <p>associations 59:9 111:22</p> <p>assume 30:10 126:17</p> <p>assuming 59:16</p> <p>assurance 19:11 73:15</p> <p>atmosphere 44:6</p> <p>attempt 169:13</p> <p>attempting 118:4</p> <p>attempts 168:8</p> <p>attend 169:13</p> <p>attorney 113:14 174:12</p> <p>attorney-client 113:14</p> <p>attractive 45:22</p> <p>audience 105:2 109:18</p> <p>audiences 78:21</p> <p>audit 23:1,10,12,18 162:13 163:8,17,18,20 164:9,11</p> <p>audits 165:20</p> <p>audit's 164:4</p> <p>August 157:15,16 164:21</p> <p>authenticated 153:18,19</p> <p>authentication 155:16</p>
--	--	--	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 5

<p>authority 33:22 34:3</p> <p>authorize 28:14</p> <p>authorized 36:15 37:3 112:19</p> <p>automatic 96:21</p> <p>availability 59:15</p> <p>available 34:7 52:9 60:21 69:11 110:19 115:10,13 131:3 140:8 150:2 151:16,19 152:8 157:3 159:2 164:10</p> <p>availing 170:18</p> <p>avenue 82:22</p> <p>average 35:7 37:2</p> <p>avoided 49:1 51:7</p> <p>awaiting 82:8</p> <p>awarded 28:3</p> <p>aware 24:22 30:14 54:21 78:13 169:17</p> <p>away 89:8 109:2,11</p> <hr/> <p style="text-align: center;">B</p> <hr/> <p>background 160:4,13</p> <p>backlog 141:9</p> <p>Baker 7:9</p> <p>ball 89:1</p> <p>Ban 10:21</p> <p>Bardot 12:3</p> <p>base 101:12</p> <p>based 46:14 47:9</p>	<p>104:22 105:1 132:22 158:14 163:6</p> <p>BASF 126:11</p> <p>basically 20:21 43:8 45:3 52:21 63:1 65:22 66:5,14,16 67:6 105:3 106:19 154:9</p> <p>basics 111:14,17</p> <p>basis 39:7 50:17,18 58:6 97:9 99:8 105:9</p> <p>Bayer 7:20</p> <p>BBEP 47:21</p> <p>Bear 97:6</p> <p>became 47:5</p> <p>become 30:2 39:15 49:13 50:18 54:7 81:4</p> <p>becoming 55:6</p> <p>beet 27:15 28:10</p> <p>beets 27:16,18 28:20 29:17,20 32:8</p> <p>beforehand 144:11</p> <p>begin 4:9 14:19 15:1 16:20 41:9 68:15</p> <p>beginning 117:8</p> <p>begun 27:22</p> <p>behalf 79:8</p> <p>behind 31:7 61:8 66:18 100:13,14,15 103:17</p>	<p>believe 26:13 75:6 115:21</p> <p>believes 118:17</p> <p>Bell 10:13</p> <p>benefit 40:5 41:2 45:9 105:4</p> <p>benefits 43:4,21 57:4 116:3</p> <p>Bennett 12:8 75:14 85:6</p> <p>Beside 45:13</p> <p>best 4:8 93:10</p> <p>Betaseed 6:15,17</p> <p>better 13:14 18:5 46:8,9 89:11 98:3 104:11 112:8 116:4 126:1 130:5 167:1</p> <p>Beuhner 7:22</p> <p>Bev 166:12 167:21 168:1</p> <p>Beverly 7:17 166:14</p> <p>beyond 45:17 47:6 155:15</p> <p>biggest 126:7</p> <p>bill 10:19 24:18,19</p> <p>bio 8:13 102:21</p> <p>biofuels 37:10</p> <p>biological 58:21 59:21</p> <p>biology 37:9</p> <p>biotech 30:21 31:16 82:20 83:1 148:15</p> <p>biotechnologist</p>	<p>3:7 36:3</p> <p>biotechnology 1:7 2:3,7 3:9 16:15 17:16 18:16 22:18 47:19,21 79:7,10 81:12 83:15 85:19 100:14 103:22 106:20 173:9</p> <p>biotechs 31:14,22</p> <p>bit 4:22 19:5 22:10 64:11 75:10 78:9,17 80:13 85:1,12 86:9,10 93:5 95:10 96:2 102:5,7 107:14 108:16 148:9 150:4 156:2</p> <p>bits 77:18</p> <p>Blanco 11:11</p> <p>Bodey 7:15</p> <p>bodies 169:22</p> <p>bolded 81:11</p> <p>bolts 22:5 26:21</p> <p>boring 17:4</p> <p>bottleneck 169:9</p> <p>bottom 84:2 116:21 144:20 145:1</p> <p>Bottoms 9:21 104:3,4,7 158:12</p> <p>Bowman 2:17 9:9 21:4 76:7,9,11,16,17 88:1,9,16 89:13 91:7 93:16 97:1 104:2 105:14,21 106:7 108:19 109:9</p>
---	--	--	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 6

<p>box 46:22 85:3 87:8 110:13,14</p> <p>boy 50:7</p> <p>BQMS 22:22 23:9 25:22 97:18,19 159:19 160:3 161:16 162:7</p> <p>brain 167:11</p> <p>branch 3:8 19:10,17,20 20:1,3 23:7,8 38:22 61:5 112:2</p> <p>branches 19:12,15,19</p> <p>break 22:3 75:6,10,11,16,18 148:9,10 159:10,15</p> <p>breaking 16:10</p> <p>breaks 4:19 18:12</p> <p>brief 76:6 148:17 170:10</p> <p>briefing 30:6</p> <p>briefings 32:12</p> <p>briefly 14:22 61:15 78:12</p> <p>briefs 30:8</p> <p>bring 18:2 54:22 55:4 89:13 109:13 116:21 117:3,6,11 171:1</p> <p>bringing 20:3</p> <p>brings 145:3,7,14</p> <p>British 17:2</p> <p>broad 42:2 141:18</p> <p>broader 55:14 141:20,22</p>	<p>142:11 168:16</p> <p>broadly 168:15</p> <p>brought 18:9 58:13 73:4</p> <p>BRS 2:10,13,16 6:13 7:1,19 9:2,9 10:13,15,17,18,2 0,21 11:1,3,4,8,10,12, 13,14,17,18,20,2 1 12:2,3,4,5,7,9,10 ,11,14,15 13:1,3,17 16:20 18:9,10 20:16,19,20 21:7,12 23:17 33:21 34:10 35:11 36:1 37:21 38:7 39:3,9,11,15 48:15 60:11 63:3 68:22 76:13,18,21 77:5,10 78:19 82:21 83:4 87:13 90:3,5,14,21 94:16,21 95:6,19 96:1 97:8,17 98:17 100:13,15 101:20 102:6 103:1 104:13,17 105:6 106:20 107:18 116:7,9,10 117:12,15 120:15 122:4 125:21 126:3 129:16 130:1 131:8 138:20 140:6 143:7,18 144:4,14,18 145:16,17 147:4</p>	<p>148:16 158:13 159:1,18 160:14 164:9 169:6</p> <p>BRS/APHIS 15:21</p> <p>BRS-only 102:13</p> <p>BRS's 87:1 91:15</p> <p>budget 21:12 24:8,16 81:8 154:9 169:21</p> <p>BUEHNER 152:6,12,17 153:3</p> <p>building 4:16 17:16 23:21 149:11</p> <p>built 49:3 89:9 158:21</p> <p>bullet 163:16</p> <p>bundle 139:16</p> <p>burn 71:20</p> <p>Burnett 11:21 13:10</p> <p>business 55:11 95:10 111:16 113:7 117:16,17,18 118:1,12,15,22 120:2 124:5 130:21 143:8</p> <p>busy 78:3 82:13 166:17</p> <p>button 116:20 145:2 151:11 165:12</p> <hr/> <p style="text-align: center;">C</p> <hr/> <p>Caceb 11:9</p> <p>cafeteria 4:16,18</p>	<p>110:16</p> <p>candid 108:20 110:8</p> <p>candy 108:4</p> <p>Cannistra 9:7,8</p> <p>capability 20:5 73:8,14</p> <p>capacity 17:17 73:6</p> <p>capital 71:20 72:4</p> <p>capturing 6:1</p> <p>card 95:10</p> <p>care 43:14 95:2 131:4</p> <p>Carlos 11:11</p> <p>carried 45:2</p> <p>carry 115:15</p> <p>Carter 47:4</p> <p>case 27:17 28:11 29:18,19 47:10 54:6 134:7</p> <p>cases 56:6 90:9,13 135:6,7</p> <p>catch-up 143:18</p> <p>categoric 34:19</p> <p>categorical 39:18 48:13 49:11,22 50:4</p> <p>categorically 34:14</p> <p>categories 99:10,11 130:13</p> <p>category 54:1</p> <p>cause 118:14,18,20 143:9</p>
--	--	---	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 7

<p>caused 53:9,11</p> <p>CBI 118:5 130:3,6,13 131:18,22 133:14 134:1,2,9 150:12</p> <p>center 1:10 9:8 87:6</p> <p>CEQ 44:3 47:8,11,12,16 49:9 50:6</p> <p>Ceres 8:19</p> <p>certain 5:6 43:21 45:10 57:15,17 70:13 115:9 122:11 132:21,22 133:3 151:8 156:19</p> <p>certainly 39:3 51:22 52:5 53:1,3 54:21 82:6 168:15 169:1,4,11,19 170:2,5 171:19 173:1,3</p> <p>CERTIFICATE 174:1</p> <p>certify 174:4</p> <p>chain 95:18</p> <p>challenge 86:1 102:7</p> <p>challenged 28:21</p> <p>challenges 167:6</p> <p>challenging 16:22</p> <p>champion 171:15</p> <p>chance 143:20 166:21</p> <p>change 18:18 19:2 53:16 96:12,13</p>	<p>101:21 157:2</p> <p>changed 18:10</p> <p>changes 3:6 18:3,8 20:6 45:20 94:13 101:22 148:18</p> <p>changing 39:13 94:21 170:12</p> <p>channel 92:4</p> <p>chart 22:4 90:21 91:2 94:19</p> <p>charts 90:4 99:7</p> <p>check 92:8 94:11 150:6 163:22 164:13</p> <p>checking 93:11</p> <p>checklists 163:19</p> <p>Chemical 6:21 32:5</p> <p>Chief 2:3 4:5 23:15</p> <p>chilling 142:12,17</p> <p>choose 72:4,5,8 73:9 88:1,2 117:12 145:13,16,18</p> <p>Choosing 87:22</p> <p>Circuit 42:17</p> <p>circumvent 139:4</p> <p>circumvention 113:2</p> <p>cisgenics 37:10</p> <p>citizen 111:21</p> <p>citizens 112:5 115:1</p> <p>claim 130:2,5,14</p> <p>claimed 131:22</p>	<p>claims 131:18 165:17</p> <p>Clapp 6:20 32:5</p> <p>clarification 120:13 139:14 143:13</p> <p>clarify 22:7 75:1 135:16 136:12,18 170:15</p> <p>clarifying 38:15</p> <p>clarity 162:20</p> <p>class 26:3,4,5 50:7 164:16 165:3</p> <p>classes 48:12 164:20</p> <p>classification 34:13</p> <p>classified 112:20</p> <p>cleaner 99:6</p> <p>clear 30:3 43:21 57:18 91:19,20 92:4 93:14 104:21 127:18,19 139:10</p> <p>clearly 40:11 43:12 44:1 52:7,8 57:14 60:20 94:4</p> <p>click 85:2 90:11 117:2,5 122:22 145:2,7 151:10</p> <p>clicked 92:15</p> <p>clicking 92:14</p> <p>clicks 107:16,17</p> <p>clients 22:17</p> <p>climate 58:20</p>	<p>169:21</p> <p>Clint 2:2 3:2 4:2,4 13:8 16:11 31:5 33:14 76:16 110:10 159:20 171:14,15</p> <p>close 4:21 23:4,18 27:12 60:22 122:9</p> <p>closed 23:10,11,13 27:11 116:10 135:7</p> <p>closely 25:1</p> <p>closes 28:17</p> <p>Coast 160:6 164:18</p> <p>Coats 7:20 123:11,17 127:20 128:1,10,15 129:3,7,14,21 130:19 132:12,15,17,19 133:21 146:5,8,19,22 147:11,14 154:13,20 155:5,18,21</p> <p>cockles 88:17</p> <p>code 95:9</p> <p>codifying 47:10</p> <p>coexistence 30:14</p> <p>coffee 4:18</p> <p>cold 30:5 108:11</p> <p>collaborating 38:10</p> <p>collaboration 116:6 171:16</p> <p>collaborations</p>
--	--	---	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 8

<p>44:9 collaborative 14:8 31:2 colleague 40:19 colleagues 56:7 169:11 collect 61:21 collection 70:6 collectively 48:19 54:8 Colleen 12:11 79:6 83:19 84:8 87:21,22 162:1 college 77:16 Columbia 42:16 combined 19:19 comes 21:7 51:20 70:13 106:1 131:15 158:7 159:10 coming 13:18 33:18 73:22 86:3 109:12 139:5 commensurate 26:13 comment 24:5 27:10 28:12,17 29:21 67:16,17 69:10 70:17 73:21 93:4 100:20 119:10,12,14 127:11 131:21 133:19 141:11 172:2 commented 103:13 commenting 94:5</p>	<p>comments 20:10 27:11 28:1 59:7,10 78:2 96:19 100:3,5 103:8 163:5,8,10 commercial 106:4 118:8 119:7 162:16 commercialized 107:7 commercially 118:7 commitment 73:16 80:22 commitments 51:10 committed 30:22 35:16 Committee 24:19,21 common 76:22 165:18 communicate 80:22 92:3 communicating 79:3 communication 93:15 106:9 communications 20:1 83:2 106:2 113:14 communities 58:21 community 161:8 162:22 companies 55:18 71:19 131:1,18 133:13 135:13 company 7:16</p>	<p>10:10 55:10 71:17 127:18 133:7 134:18 154:5,7,15 155:11,12 156:5,14,17 company's 122:11 compared 104:13 comparisons 58:6 competitive 118:14,18,20 119:7 competitiveness 56:22 competitors 130:12,16 complaint 96:5 complement 161:11 complete 15:18,22 28:9 66:13 67:9 68:2,3 132:21 133:5 142:10 146:22 147:7 completed 29:6 50:15 59:16 79:13 completely 119:11 150:13 completes 39:11 60:10 completing 28:6,16 29:19 64:16 complex 18:6 36:12 64:18 96:9 complexity 17:18 24:1 36:8,10 37:5</p>	<p>compliance 17:20 19:9,10,11,17 22:12 23:6 25:21 31:19 35:10,14 42:22 72:1 78:22 156:12 160:15,16 161:3,8 162:22 165:10 compliance- assistance 161:6 compliant 164:2 complicated 150:5,18 comply 112:1 components 64:12 concept 29:21 154:14 concepts 29:7 concerned 46:1 concerning 114:10 concerns 43:15 49:19 55:1,21 56:4 141:3 concise 50:8 conclude 38:13 concluded 17:8 163:3 173:11 conclusion 17:7 51:1,2 59:17 concurrent 165:20 condition 98:5,7 114:5 conditions 49:5,10 conduct 160:21 161:18 conducted 161:9</p>
--	--	--	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 9

<p>conductive 126:5 130:2</p> <p>confidential 111:15 113:7 117:16,17 118:10 124:4 126:12,16,20 130:21</p> <p>confidentiality 130:15</p> <p>confine 50:2</p> <p>confinement 49:6</p> <p>confuses 100:19</p> <p>confusing 90:8,10</p> <p>confusion 88:7</p> <p>Congress 41:8 43:17,20 44:3 45:14 112:5</p> <p>consequence 49:8 53:17</p> <p>consequences 42:20,21 43:3 46:15,21 57:20 58:3,15</p> <p>Consequently 45:4</p> <p>conservative 134:2</p> <p>consider 23:3 40:22 41:10,11 43:10 54:15 56:1 61:17 86:22 137:18 145:9</p> <p>consideration 42:13 165:4</p> <p>considerations 54:17</p> <p>considered 49:21 50:5 51:19 53:2 57:8 59:18 60:15</p>	<p>134:1</p> <p>considering 61:6</p> <p>considers 43:11</p> <p>consolidate 165:6</p> <p>consolidated 95:10</p> <p>constant 98:15</p> <p>constituents 40:11 44:6 53:5</p> <p>constitute 113:21</p> <p>constructs 36:11,13,15,18 37:2</p> <p>consult 74:18 122:4</p> <p>consultant 9:18 71:13</p> <p>consulting 56:10 69:12 124:1 125:2</p> <p>consume 35:14</p> <p>consumers 57:4</p> <p>contact 22:8 92:8,11 94:15 95:5,9 98:12 99:8 101:3 116:22 127:10 145:4 151:3,17 165:2</p> <p>contain 124:4</p> <p>contained 37:2 114:4</p> <p>contains 40:1 163:18</p> <p>content 16:6 87:7 101:19 107:21 108:6</p> <p>context 33:20 55:14 134:14</p>	<p>168:15,19 169:4 171:3</p> <p>Contingent 26:7</p> <p>continue 5:4 15:9 17:21 20:2 25:9,21 79:20</p> <p>continuing 24:12 169:1</p> <p>contract 20:9 26:20 28:4 73:7 118:4</p> <p>contracted 20:7</p> <p>contracting 24:4</p> <p>contractor 65:2 148:16 152:19</p> <p>contractors 38:3</p> <p>contracts 117:21</p> <p>contrast 103:21</p> <p>contribute 141:8</p> <p>contributing 44:21</p> <p>control 19:14,16 131:13 148:19 156:15</p> <p>controls 103:16</p> <p>controversial 49:13</p> <p>conventional 30:21 57:2 58:18</p> <p>conversation 33:11 75:4 86:17 87:19 88:6 89:6</p> <p>conversations 4:22 167:14</p> <p>cooperative 64:22 68:9</p> <p>cooperators 56:13</p>	<p>coordination 2:17 19:18 21:1,5 76:8,19 79:9</p> <p>coordinative 56:7</p> <p>copies 135:13</p> <p>copy 119:2 126:22</p> <p>copying 96:19 115:10</p> <p>Cordts 12:15</p> <p>core 41:1</p> <p>corporate 155:15 158:12</p> <p>corporation 112:5</p> <p>correct 127:4 150:7 152:16,17</p> <p>corresponding 138:7</p> <p>cost 43:6 62:18 64:16,20 65:10,13,16,20</p> <p>cost-sharing 71:14</p> <p>Cotton 9:1</p> <p>Council 9:1 44:3,14 45:5</p> <p>counsel 174:9,12</p> <p>count 23:4 46:9</p> <p>country 30:16</p> <p>counts 25:6</p> <p>couple 4:9 69:9 140:20 149:15 162:19</p> <p>course 15:11,15 29:6 34:10,12 35:16 40:5 42:2 46:8 50:19 51:4 56:1,16,19 57:5 58:4 59:8 60:11</p>
---	--	--	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 10

<p>78:15 99:5 107:18 131:22 149:21 162:2 163:9 167:14</p> <p>courses 130:10</p> <p>court 5:9,10 27:7,17,19 28:5 29:13 30:7,10 32:12 42:16 47:11 119:19 125:14 127:2,6 133:12 134:15 174:1,19</p> <p>courts 29:13 45:7 112:5</p> <p>cover 26:6 77:4</p> <p>covered 108:17</p> <p>CR 154:9</p> <p>Craig 2:11 12:22 33:16 38:20 39:1 61:1 64:17</p> <p>create 18:19 19:3,17 44:14 47:17 53:18 63:2,13 64:4 72:20</p> <p>created 19:9,11,14 44:4 57:8 112:12</p> <p>creates 115:1</p> <p>creative 72:19 167:7</p> <p>credentials 75:15</p> <p>criteria 138:1</p> <p>critical 90:7</p> <p>crop 17:20 22:13 28:22 49:20 50:2 53:19,20 54:13 58:18</p>	<p>crops 54:11,12</p> <p>CropScience 7:21</p> <p>cross-link 95:20</p> <p>crux 103:11</p> <p>cumulative 53:8 54:9,14</p> <p>Cumulatives 54:1</p> <p>curious 105:6 137:17 138:6 153:13</p> <p>currency 79:15</p> <p>current 15:4 33:21 79:1 101:12 103:14,15 134:7 168:10</p> <p>currently 67:13 96:18 121:12</p> <p>customer 63:8 95:14</p> <p>customers 40:6 55:3</p> <p>cut 96:18</p> <p>cutoff 139:22 140:1,3</p> <p>Cyndi 131:12</p> <p>Cynthia 131:7,12</p> <hr/> <p style="text-align: center;">D</p> <hr/> <p>damage 42:6</p> <p>Dan 8:20 102:9 137:16</p> <p>data 66:10 69:21 79:14,17 80:8 82:14 83:15 84:14,15 85:6 93:12 113:1 114:9 150:21 151:2</p>	<p>data.gov 78:18 84:9,19</p> <p>database 79:12 100:5,6,8 114:19 121:9</p> <p>databases 100:7 107:22</p> <p>dataset 84:13</p> <p>datasets 84:20,22</p> <p>date 18:3 26:6 81:16 92:11 100:16,19 101:16 119:17 120:2</p> <p>daughter 77:15</p> <p>Dave 6:22 8:2</p> <p>David 8:5 12:18 38:1</p> <p>Dawn 8:11 12:5</p> <p>day 5:2,6 15:9,12,15,17 16:17 17:8,11 21:17 78:4 87:3 102:21 127:13 140:2 151:15 157:2 159:15 166:17 167:14</p> <p>days 102:7 106:21</p> <p>dead 90:16</p> <p>deal 18:6 23:22 24:15 25:5 29:9 39:4 71:15 138:5 141:1 142:13 169:17</p> <p>dealing 14:14 45:11 131:14 141:18</p> <p>deals 15:20</p>	<p>dealt 14:4 98:2</p> <p>December 1:13 28:18 32:13</p> <p>decide 29:5,12 49:22 162:12</p> <p>decided 41:9 43:4 97:7 149:15 156:1 158:19</p> <p>decision 27:8,18,19 28:8 29:3 58:5 120:6,8 124:16 127:4,6,7 133:20</p> <p>decisionmakers 40:13 43:2 59:20</p> <p>decisionmaking 42:15</p> <p>decisions 18:22 20:13 32:10 41:11 43:1 45:15 46:9,14 48:5 115:17 133:14 140:5,9,13 160:20 161:9</p> <p>declarations 30:8</p> <p>decrease 65:16</p> <p>deemed 67:8 68:2 132:20 133:4</p> <p>deep 92:15</p> <p>deeply 33:15</p> <p>default 153:20</p> <p>defensible 37:17</p> <p>defined 29:22 54:2</p> <p>defining 164:1</p> <p>definitely 55:12 103:22</p> <p>defunct 90:9,17</p>
--	---	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 11

Dehubert 12:10	142:11	163:15	105:10
delayed 53:18	design 86:3,5 99:15 154:10 156:11	developer 74:3	digestible 103:3
delivers 167:8	designated 120:2	developers 39:7 54:21 74:17	direct 53:8,21 58:9 172:19
delivery 80:21	designed 34:18 154:22 161:10 162:14	developing 18:20 62:16 64:6 72:9,17 75:2 149:3 150:19 164:6	directed 42:19
demand 115:2	designing 154:8 158:18	development 11:6 12:1 18:21 21:7 74:4 83:15 162:8,16 163:11 164:5	direction 46:18 174:7
demands 36:6	despite 42:22 159:20	develops 40:4	directly 45:2 69:13 128:17
democracy 114:12	destroying 32:7	device 99:16 118:8	director 2:9,17 3:11 20:21 21:2,4,11 33:5 76:7,18 122:17 159:17
demonstrate 49:21	destruction 32:7	devices 99:15	disagreeing 126:21
dense 96:9	detail 58:4,11 104:17 113:10 119:6 157:1	devote 71:17	disclose 112:15 113:22 115:8 133:3
department 1:5 29:4 32:9,11 72:15 161:17 168:15	detailed 34:16 51:4 105:9	devoted 18:20 24:11	disclosed 119:16,18 122:5 133:4
depending 94:1 126:21 135:13	details 41:12 81:17	Dick 9:2 105:22	disclosure 112:16,17 118:6,19 122:1,4
depends 122:10 147:1,6	determination 74:19 124:21 134:12,17 138:11,16 139:6	dictate 34:4	disclosures 115:22
deposition 174:7,10	determinations 140:7,8	dictates 34:7 156:13	discovered 56:9
deprive 113:19	determine 48:16 50:10 60:18 62:17 65:11,17 127:9 138:14,19	difference 121:3 132:2,3,5	discretionarily 122:5
Deputy 2:6 6:13 7:18 31:20	determined 17:3 44:2 51:3	different 14:17 30:1 65:8 72:18 74:16 76:19 90:19 92:2,6 100:11 105:3,4 130:13,15 138:10,18 139:8,9 143:14 156:16 158:16	discretionary 115:22 122:1,4 123:18 125:8,18
deregulate 27:18 29:12 52:21	determines 131:15	differs 47:15	discuss 5:7 15:4 55:8 57:21 104:13,18
deregulated 50:21 107:6 133:2	determining 44:20 51:17 60:19 127:14	difficult 85:16 92:19 94:11 97:16 103:12	discussed 52:22 54:19 58:3 168:14 169:21
deregulation 17:21 22:13 27:8 28:14 29:10,14,20,22 30:2 34:12 52:22 133:5	develop 69:16 73:6		
deregulations 29:15 35:5	developed 83:12		
Desagun 8:18			
describes 79:9			
describing 141:12			

<p>discussing 5:4 40:18 55:20 56:6 170:6,14</p> <p>discussion 5:2,3,16 6:2 15:9 16:3 53:4 76:6,14 160:8 169:2</p> <p>discussions 2:18 5:21,22 37:12 104:20 168:16</p> <p>dislikes 103:11</p> <p>distance 53:12</p> <p>distinction 131:5</p> <p>distribute 130:8</p> <p>distributed 144:10</p> <p>District 42:16</p> <p>dive 104:17 105:8</p> <p>diversity 58:21</p> <p>division 2:9 3:11 20:20 33:5 76:7 159:16</p> <p>divisions 18:15,17</p> <p>dockets 20:11</p> <p>docking 85:16</p> <p>document 28:2 33:17 34:20 46:19 48:10 50:9 56:16 59:14 60:13,14 62:19 63:10,17 67:5 101:11 127:21 128:7 129:2 131:13</p> <p>documentation 65:17 66:15 68:11 140:6 150:20 151:5,13</p>	<p>documents 18:21 20:12 24:6 35:4 37:16 38:4,8,13 46:8 64:6,17 65:5,10 66:2,3 67:19 73:9,14 74:2,6 101:7 102:7 103:6,17 112:13 120:21 121:1,4 122:5 124:12 125:1,21 131:2,3,8,16 138:13,14 139:15 140:15 143:21 144:3,9 145:17 164:10,12 165:9,13</p> <p>Dohrmann 8:14</p> <p>Doley 10:19</p> <p>domain 128:9</p> <p>domestic 59:3 162:8,15,16</p> <p>done 17:3 25:6 47:18,20 49:11 50:17 56:14 60:20 118:2 124:8 126:2 144:21 150:5 154:10</p> <p>donuts 4:17,18</p> <p>Dover 7:8</p> <p>Dow 7:5,7,9,11,22 8:11 10:3,5</p> <p>download 84:21 85:12 89:22 115:6</p> <p>downloaded 91:4</p> <p>downloading 99:17</p>	<p>Dr 23:8 160:3 165:2</p> <p>draft 27:9 28:7,11,17 52:15 59:6,12 63:15 67:14 163:8,16</p> <p>drafted 161:16</p> <p>drill 26:21</p> <p>drive 80:16 81:1</p> <p>driven 82:7</p> <p>driving 80:11</p> <p>due 32:12 94:10 127:5</p> <p>Dunahay 11:7</p> <p>Dunkin 4:17</p> <p>DuPont 6:19 7:3 89:16</p> <p>during 15:11,15 18:12 56:2 63:4 68:11 139:16 160:21 161:16 163:9 167:13</p> <hr/> <p style="text-align: center;">E</p> <hr/> <p>EA 29:20 39:16,17 48:15 49:11,14,15,17,2 2 50:14,16,18 51:2,8,12,22 52:14,15,20 54:19 56:16 59:6,12,13 60:10 63:15 67:14,17 68:6</p> <p>earlier 73:21 80:4 103:13</p> <p>early 13:21 20:21 63:3,14,18 149:13</p>	<p>EAs 39:19 53:2</p> <p>ease 93:12</p> <p>easel 86:19 87:17 89:5</p> <p>easels 86:18 88:3 89:1</p> <p>easier 16:5 86:10 130:1</p> <p>easiest 166:19</p> <p>easily 130:8</p> <p>easy 32:20 96:10</p> <p>eat 110:16</p> <p>e-authentication 154:3 155:14</p> <p>Eck 131:12 132:9 133:7,10,13,22 135:15,18,22 136:2,4,9,14,17 143:12,16</p> <p>economic 59:3</p> <p>ecosystems 53:19</p> <p>Ed 9:5 23:8</p> <p>Edenspace 12:18</p> <p>EDWARD 9:5</p> <p>effect 65:11 142:12</p> <p>effective 108:17 167:7</p> <p>effectively 60:15 169:20</p> <p>effectiveness 65:9,19</p> <p>effects 51:6 53:18 58:9,10</p> <p>efficiencies 62:20 72:20</p>
--	--	---	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 13

<p>efficiency 65:9,15 66:21 137:21</p> <p>efficient 165:6 167:7</p> <p>effort 15:16 79:16 161:10 163:4</p> <p>efforts 25:9 42:5,7 160:16</p> <p>EFOI 121:6</p> <p>eFOIA 78:14 84:1 90:11 114:14,21,22 117:3,4,16 121:2 128:4 136:12,21 143:20 145:7,11</p> <p>eight 135:9</p> <p>EIS 27:11 28:4,7,17 29:19 43:22 47:2,6 50:17,18 51:22 52:19 68:6</p> <p>either 34:14,21 48:18 68:3,6 110:16 130:11 134:4</p> <p>elaborate 171:10</p> <p>electronic 111:15 112:14 115:13 145:12 174:19</p> <p>electronically 149:6,9,12</p> <p>electronics 112:14</p> <p>elements 150:21 151:2 152:15</p> <p>eligible 65:21 67:18</p> <p>eliminate 42:6</p> <p>else 6:4 90:18 101:6 107:9</p>	<p>143:16 146:2 159:4</p> <p>elusive 95:8</p> <p>email 83:9 95:7,15</p> <p>embedded 19:1</p> <p>embraced 44:2</p> <p>embraces 43:19</p> <p>emerged 29:8</p> <p>Emery 9:6</p> <p>Emmy 106:7</p> <p>Emmys 106:8</p> <p>emphasis 43:7 80:5</p> <p>emphasizes 48:21</p> <p>employ 161:13</p> <p>employed 174:9,12</p> <p>employee 154:22 155:12 174:12</p> <p>employees 18:9 20:19,20 31:13</p> <p>encompass 140:19</p> <p>encourage 18:12 22:2 60:11 62:7,14 63:19,21 173:1</p> <p>encouraged 56:2 59:22</p> <p>encouragement 57:10</p> <p>encourages 118:12</p> <p>endanger 114:1</p> <p>endangered 60:4</p> <p>endless 90:10</p> <p>energy 88:19</p>	<p>enforced 45:4</p> <p>enforcement 113:16,17,19,22 160:17 161:11</p> <p>engage 56:3,13 124:3</p> <p>engagement 116:5</p> <p>engagements 173:3</p> <p>engine 93:7 96:2 102:13,14</p> <p>engineered 18:1 57:3 81:12</p> <p>enhance 46:16</p> <p>enhancements 149:16</p> <p>enhancing 43:13</p> <p>enjoin 127:2</p> <p>enroll 22:19 71:2</p> <p>enrolled 22:21 26:1,2 71:1</p> <p>enrollment 165:1</p> <p>ensure 17:22 42:21 43:1 115:12</p> <p>ensures 40:13</p> <p>ensuring 22:13 35:17</p> <p>enter 72:4</p> <p>entire 65:3 101:19</p> <p>entirely 138:4</p> <p>entirety 147:4</p> <p>entities 20:15 22:19,21 26:2,4 73:9 130:12</p> <p>entry 93:13</p>	<p>environment 27:7 35:20 40:3 41:14,18 42:6,9,11,21 43:13 46:17 57:4,6,7 58:13,19 59:3,4,21</p> <p>environmental 2:8,9,12,14 11:16 15:21 18:17 20:2 21:2 27:10,13,20,21 28:12,16 31:18 33:5 34:6,15,16,22 35:8,18 38:21 41:10 42:14 43:3,6,10,16,18 44:3,14 45:5,11 46:15,21 48:18 49:8 50:3,8,11,15 51:1,5,6 52:6 55:17,19 56:4 57:19 58:2,3,10,15 60:2 61:4 63:5 64:8,9,12 65:12 66:2,3,15,17,18, 20 67:2,5,9,10,20 68:5 70:2 72:10,15,17 73:8</p> <p>envisioned 43:20 44:5</p> <p>EPA 56:8 79:9 96:3 130:14</p> <p>ePermit 98:10</p> <p>ePermits 3:6 16:15 75:13 93:20 94:8 95:3,12 96:15</p>
--	---	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 14

<p>100:21 110:19 148:17,19 149:4,6,8 151:4 156:20 158:22</p> <p>equaled 116:11</p> <p>error 98:10</p> <p>Errors 98:9</p> <p>ESI 51:4</p> <p>especially 13:19 94:20 98:17 100:6,16 102:12</p> <p>ESs 39:18</p> <p>essential 102:4</p> <p>essentially 89:17</p> <p>establish 26:18 47:3 57:14</p> <p>established 23:6 44:10 47:1 111:18 143:17</p> <p>etcetera 91:17 92:3 96:4</p> <p>eucalyptus 30:6</p> <p>evaluate 20:10 61:21 163:13</p> <p>evaluated 163:10</p> <p>evaluates 119:9</p> <p>evaluating 24:5 66:9</p> <p>evaluation 160:17 163:4 172:12</p> <p>evening 100:22</p> <p>eventful 167:3</p> <p>events 4:6 17:7</p> <p>eventually 128:3</p> <p>everybody 13:5,17 77:1 87:3 89:5</p>	<p>91:19 125:11 166:17 172:10</p> <p>everybody's 157:6 166:4</p> <p>everyone 4:3 5:14 13:18 33:14 61:7 104:14 148:13 149:7 156:5 165:7 167:21</p> <p>everyone's 149:9 165:18</p> <p>everything 5:11 100:13 108:17 154:16</p> <p>evidence 30:11 50:9</p> <p>evolve 30:3</p> <p>exact 81:16</p> <p>examination 114:5</p> <p>examine 30:11 65:4</p> <p>examined 28:3 35:18</p> <p>examining 17:7</p> <p>example 20:10 45:19 49:4,12,17 51:19 53:14,19 54:10 57:12 92:14,19 95:21 117:13</p> <p>examples 105:5</p> <p>Excel 85:5 89:22 91:3</p> <p>excellent 46:10,13 165:16</p> <p>excerpts 83:3</p> <p>excited 72:16</p> <p>exciting 16:21</p>	<p>excluded 34:15</p> <p>exclusion 34:19 48:14 49:11 50:1</p> <p>exclusions 39:18 50:4</p> <p>excuse 35:21</p> <p>Executive 14:2,5,9 47:6 60:8 112:2,19 117:21 120:1 124:9</p> <p>exempt 113:4</p> <p>exemption 112:18,21 113:3,6,8,11,16 114:3,8 118:5,10,15 119:5 120:9</p> <p>exemptions 112:17 142:9</p> <p>exercise 165:21</p> <p>exercises 163:13</p> <p>existence 94:20</p> <p>existing 45:21 47:10 139:14</p> <p>expand 34:2</p> <p>expanded 47:6</p> <p>expectation 167:4</p> <p>expectations 162:21 163:18 164:4</p> <p>expected 81:20</p> <p>expecting 82:15</p> <p>expense 65:1 71:22 73:8,15</p> <p>experience 21:8 37:22 39:4 74:21 103:20 106:1,9</p>	<p>129:22</p> <p>experienced 37:20</p> <p>explain 119:15 151:11 156:22</p> <p>expressed 26:4</p> <p>extended 24:14</p> <p>extensive 21:8</p> <p>extent 39:13 44:20 62:17</p> <p>extraordinary 49:10</p> <p>eye 108:4</p> <hr/> <p style="text-align: center;">F</p> <hr/> <p>face 45:12 109:3</p> <p>faces 167:17</p> <p>facilitating 48:5</p> <p>fact 29:10 39:16 40:13 47:19 49:16 50:12 53:12 55:18 99:3 136:19 155:14</p> <p>factor 137:18</p> <p>factors 42:14 43:10</p> <p>Fair 168:4</p> <p>fairly 91:6 94:9 96:11 106:14</p> <p>fake 150:8,9,11</p> <p>fall 24:17 149:13</p> <p>falls 62:8</p> <p>false 159:22</p> <p>familiar 77:11 81:4 89:21</p> <p>familiarity 49:20</p> <p>FAQ 102:8</p>
---	---	---	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 15

<p>farm 56:11 57:4</p> <p>fascinating 105:15</p> <p>fashion 38:8</p> <p>faster 155:22</p> <p>favor 29:1</p> <p>fax 117:1</p> <p>FDA 56:8</p> <p>feature 82:21</p> <p>February 26:3,5 164:20</p> <p>Federal 23:1 28:1 40:7 41:9 42:7,12 43:1 44:8,17 45:6,9,15 47:3,12,14 56:3 59:15 68:13 79:2 80:14,22 91:13 111:19 112:2,14 113:4 163:9 164:15</p> <p>feed 77:20,22 78:6</p> <p>feedback 2:19 16:4 77:7 85:15 86:12 87:20 110:8 163:6 172:21</p> <p>feeds 59:1</p> <p>feel 61:8 85:20 86:3 87:10 123:20 127:3 164:13</p> <p>feeling 107:1,12,16,21 108:2</p> <p>feels 108:11 170:21</p> <p>felt 21:22 93:19</p>	<p>95:12,19</p> <p>FEMALE 12:19 124:18 125:3 137:4,9,11 148:21</p> <p>Ferguson 10:16 21:10</p> <p>field 33:9 149:6 150:10 151:9 157:11,13 161:9</p> <p>figure 109:10</p> <p>figured 161:1</p> <p>file 30:9 89:22 91:3,5 100:11,13 111:20 133:4</p> <p>files 139:15</p> <p>fill 156:9</p> <p>filling 172:11</p> <p>final 22:22 27:12 28:7 52:19 59:13 67:17 115:15 120:7 149:5 156:8</p> <p>finalized 151:4</p> <p>finally 35:15 48:7 92:16</p> <p>financial 23:15 73:11 114:7 118:9</p> <p>financially 174:13</p> <p>finding 50:12 90:6 103:7</p> <p>fine 81:18 97:4</p> <p>finger 37:9</p> <p>finish 154:11 155:9</p> <p>finished 47:13 122:12 126:17</p>	<p>154:15</p> <p>finishing 27:12</p> <p>first 14:2 15:6,18,19 18:15 22:16 27:5 33:3 39:1 40:9 41:6 48:14 51:14 52:16 54:19 56:19 58:13 69:9 88:21 97:8 107:18 111:3 121:7 124:20 125:2 128:2 129:7 132:20 145:18 159:14 161:21 162:11</p> <p>fiscal 22:11 23:2 24:8 116:7,10 120:17</p> <p>Fish 60:7</p> <p>Fitzpatrick 8:9,10 93:18,19 122:19,20 123:6 125:7 126:9 134:22 139:13,19 156:4,21 170:9</p> <p>five 22:19 31:18 63:1 92:15 161:19</p> <p>five-star 85:7</p> <p>fixable 107:19</p> <p>fixed 109:14</p> <p>flavors 74:16</p> <p>flexibility 45:11</p> <p>flipcharts 6:2</p> <p>floor 4:10 5:17 166:2 168:6 170:8</p>	<p>flow 58:21 94:19</p> <p>flowing 43:5</p> <p>fly 134:4</p> <p>focus 14:1 15:2,19 25:10 35:11 39:15 40:9 41:17 46:2,4,19 55:7 59:2 60:12 160:9 172:14 173:3</p> <p>focused 17:15 29:19 35:3</p> <p>focusing 56:15 80:17 94:8</p> <p>FOIA 16:14 78:16 84:4,5,6 111:4,5,14,15,17 ,18,20 112:1,4,6,17 114:11,17 115:3,12,14 116:1,8,10,14,15 ,21,22 117:6,7,14 118:5,6,17 120:7,15 121:8 124:7,15 125:18,19,20 128:11,13 129:10,16,17 130:4,22 131:15,16 132:4 134:11,14 135:14 138:10,15 139:2,7 140:20 141:8 142:1,2,5 143:1 144:16,18,22 145:2,3,12,19,22 146:8,21 147:4,5,7</p> <p>FOIAs 129:13</p>
--	---	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 16

<p>143:14 144:8 folks 6:8 76:3 78:12 83:2 86:15 88:13 100:1 122:10 161:3 165:16 172:4 FONSI 50:12,14,19,22 59:14 Food 6:20 32:5 footing 77:1 Forage 8:6,8 foregoing 174:4 foreign 111:21 foreseeable 53:13 54:4 forged 44:7 forget 69:4 form 105:1 formal 33:4 65:14 140:22 168:22 formalize 61:21 70:5 formalizing 64:11 formally 70:15 format 84:15 95:11 formed 37:19 38:22 former 159:16 forms 172:12 formula 118:7 forth 44:18 forward 55:4 106:10 117:9 138:11,12</p>	<p>139:20 157:2 171:19 forward-looking 157:1 foster 46:12 fourth 58:22 framework 56:7 frankly 25:8 free 164:13 Freedom 3:3,4 111:10,11,17 122:17 freely 130:11 frequency 91:11,22 frequent 115:21 frequently 91:4 98:14 100:2 101:22 125:22 138:15 141:21 Friday 21:18 24:13,14 friend 93:8 friendlier 108:16 friends 82:16 front 4:14 87:12 88:4 166:12 fruit 109:1 full 24:20,21 26:3 28:16 131:21 138:12 164:21 fullest 42:22 full-redacted 126:22 fully 41:10 43:3 44:2 52:21</p>	<p>fun 86:17 function 19:13 40:2 94:21 96:18 160:15 161:6 functional 151:19 functionality 85:18 94:14 95:12 100:4 153:6 functioning 96:6 functions 44:15 93:22 161:12 fund 24:13 fundamental 105:2 109:17 funding 24:9,10 26:7 67:16 68:9 future 40:21 54:4 61:17 69:12 74:20 168:8,11 172:14 173:3 FY'10 122:10 135:7</p> <hr/> <p style="text-align: center;">G</p> <p>Gabel 2:14 13:2,3 33:18 40:19 61:3,7,10 68:19 69:14 71:2 72:2 Gail 4:14 gain 74:20 gateway 154:4 GE 22:14 25:13 27:9 49:6 58:17 162:8,17 gene 58:21 general 33:11 36:3 69:1 95:5,19</p>	<p>103:3 104:9 105:7 107:1,16 130:16 generally 34:18,19 92:1 100:1 102:14 103:10,18 107:12,13 129:1 generate 46:10 generic 91:2 genetically 17:22 57:3 81:12 Genetics 8:6,8 genomics 37:8 geographic 165:5 geological 79:8 114:9 George 9:2 105:22 106:12,17 get-go 130:3,6 133:15 gets 131:20 132:19 142:11 getting 20:9,16 36:9 66:9,22 70:20 75:22 80:20 85:7 103:6,11 104:11 138:1 166:4 173:4 Gibson 11:14 Giddens 9:17 71:12 Gilbert 70:11 73:20 99:22 120:13,17,20 121:6,14,22 122:3 136:13,16,18</p>
--	---	--	---

<p>137:2 140:4 146:18 168:7 171:10 Gill 8:11 Gina 7:22 given 43:9 71:18 145:22 174:8 gives 45:10 84:20 102:11 116:22 119:18 giving 66:20 glad 151:2 Glen 10:9 glitches 149:14 glossary 98:16 goal 22:19,22 26:1,7 43:12,17 57:1 62:15 65:7 121:20 162:3 goals 81:1,3,10 162:19 gone 37:2,3 90:2 123:15 124:22 132:21 135:12 142:1 Google 90:15 91:15 93:8 97:13 gorgeous 108:5 Gosh 142:3 gotten 85:15 86:2 governed 119:22 140:18 government 14:5,6,7,8 19:20 30:9 40:2 41:20 44:17 80:2,6,15 81:1 84:11 95:21 111:20 112:3,4</p>	<p>113:3 114:15 117:19 118:3,4,11,13,16 ,21 161:15 governments 111:22 Government's 124:16 governor 170:22 grab 86:19 grain 157:22 granted 98:3 graphics 36:19 108:2,7 great 21:8 39:4 71:15 88:20 104:15 105:22 110:4 169:17 171:6 greater 49:14 59:2 greatest 79:18 Greg 7:11 9:19 11:4 Gregoire 2:6 4:11 6:12 13:6,7,12,14,16 17:6,11,14 21:22 31:9,15 32:2,10,19,22 52:22 73:2 170:10 171:6 172:4 Gregory 7:11 9:10,19 11:4 ground 29:3 group 2:18 76:6,14 88:4,21 89:16 91:11 94:18 102:20</p>	<p>105:12 106:13 107:20 112:9 155:1 163:10 groups 5:22 64:1 86:14 88:6 89:6 105:3,11 grow 19:4 growing 17:17 18:6 23:22 guess 72:18 76:8 85:20 99:13 120:17 142:15 157:14 168:18 guidance 69:11,16,19 70:7 92:8 101:6,7,11 guidelines 47:2,4 69:19 86:3,7 109:11 114:1 164:3 guides 86:4 Gupta 10:14 Gutsche 7:2 guys 79:5 82:11,20 85:22 88:16 105:19 110:3 152:13 156:15 172:20 Gwen 11:21 Gwen's 13:8 <hr style="width: 20%; margin: 10px auto;"/> <p style="text-align: center;">H</p> <hr style="width: 20%; margin: 10px auto;"/> half 16:11 94:5 102:22 110:20 131:14 Hall 10:1 102:19 hand 5:17 21:5,10 53:11 86:20 87:8,9 110:10</p>	<p>142:20 hand-helds 5:15 handle 17:17 19:21 handled 149:8 handles 21:12 Handley 3:7 12:4 148:13,14,22 149:2 152:2,10,13,18 153:12,15 154:19,21 155:6,20 156:3,10 157:3 158:15 159:8 handling 140:14 handouts 86:21 88:10 hang 96:11 hanging 109:1 happen 24:14 70:22 108:13 129:1 157:9 happened 140:1 160:10 165:14 happens 134:10 happy 22:7 31:5 hard 35:17,19,22 80:19 84:3 97:22 99:15 108:12 152:4 harder 109:3 harm 42:18 118:14,18,20 143:9 harmonize 165:17 harmonizing 42:8</p>
---	---	--	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 18

<p>Harold 11:13</p> <p>haven't 66:14 114:17 123:15 124:22 151:1 156:10</p> <p>having 25:4 60:20 65:14 68:13 69:19 78:6 85:8 92:3 93:14 95:2 99:10 106:10 124:22 142:9,17,18 155:15,22 156:5</p> <p>head 21:1 23:8 110:4 156:12</p> <p>health 1:6 58:22 59:1</p> <p>hear 13:8,10 19:5 61:7 81:21 88:20 111:8 120:1 125:11,14 126:16,18 127:6 134:16 168:7</p> <p>heard 16:22 81:21 102:4 159:21 160:3</p> <p>hearing 30:11 97:13 110:5</p> <p>heart 51:12,22 88:17</p> <p>held 47:11</p> <p>Helena 4:14</p> <p>He'll 33:6</p> <p>Hello 5:10 75:21 104:3 148:13</p> <p>help 20:10,11 38:4,7 46:14 63:11 64:13 69:22 72:16 80:16 85:14,22</p>	<p>96:3 150:19 156:2 161:7,20 163:13 169:19 170:4 172:5</p> <p>helped 90:15</p> <p>helpful 56:12 69:8 92:5 94:4,22 95:4,20 96:16,22 107:22 140:7,15 155:19 172:12</p> <p>helping 106:4 160:6</p> <p>helps 84:16 163:12</p> <p>herbicide 53:20 54:12</p> <p>herbicides 53:21</p> <p>herbicide-tolerant 53:19</p> <p>hereby 174:4</p> <p>here's 105:7</p> <p>hereto 174:13</p> <p>Heron 8:2,3</p> <p>he's 5:9 30:16,22 33:5 75:17 141:22 171:16</p> <p>Hey 31:12</p> <p>HHS 79:9</p> <p>hi 61:8 93:18 97:3 99:22</p> <p>high 71:20 171:19</p> <p>higher 38:7</p> <p>highlight 126:19</p> <p>high-performance 80:2</p> <p>high-performing 80:6</p> <p>high-priority</p>	<p>81:3,9</p> <p>high-value 84:13</p> <p>hired 20:18 24:1</p> <p>hiring 65:2</p> <p>historically 36:1 41:7 49:16</p> <p>history 17:4 89:9 102:6</p> <p>hit 108:21 109:16 116:20 117:9 160:5 165:12</p> <p>hold 38:16 99:9 112:21 113:11 130:9</p> <p>holder 154:18</p> <p>holders 158:6</p> <p>holding 14:10</p> <p>hole 101:17</p> <p>home 17:1</p> <p>honest 133:16</p> <p>honored 85:20</p> <p>hook 166:7</p> <p>Hooker 11:4</p> <p>hope 31:21 34:2 63:12 151:14</p> <p>hoped 149:12</p> <p>hopefully 21:18 68:15 166:22 167:7</p> <p>hoping 86:7 107:7 153:7</p> <p>hot 79:1 115:20 137:17 141:3</p> <p>hour 16:11 110:20</p> <p>hours 78:4</p> <p>house 24:21</p>	<p>67:8,14</p> <p>hovering 36:22</p> <p>Howie 126:10,14</p> <p>HPPG 81:5</p> <p>HPPGs 81:3,7,9</p> <p>Huff 12:6,7</p> <p>huge 132:12</p> <p>human 58:22 108:12</p> <p>hundred 36:17</p> <hr/> <p style="text-align: center;">I</p> <hr/> <p>Iadicicco 11:5</p> <p>I'd 4:2 54:16 60:21 93:11 106:2 108:19 109:4</p> <p>ID 157:17 158:2,8</p> <p>idea 66:18 161:6</p> <p>ideas 14:16 40:21 55:2 110:4 173:2</p> <p>identifies 51:9 59:6</p> <p>identify 51:6,15 52:8 53:6 63:5,10 119:4</p> <p>identifying 54:18</p> <p>IDs 157:9</p> <p>ignoring 169:3</p> <p>II 44:15</p> <p>I'll 4:7 5:16 15:1 18:11 31:5,9 33:1 36:11 38:13 61:13 74:12 76:15 104:18 121:22 151:2,3 152:20 160:7 162:5 163:2</p>
--	--	---	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 19

<p>167:18 illustrate 108:6 I'm 4:4,5,9 6:12 7:18 10:9 12:22 13:2 14:21 20:17 24:13,22 33:15 55:11 61:11,15 74:4 76:17,19 77:10 78:2,16 83:11,20 87:4 89:9 93:18 97:3 98:20 99:20 108:4 110:9 111:9,11 116:17 122:8,16,17 125:12 131:9,12,13,15 133:10 137:16 138:6 144:17 145:18 147:3 148:14,15 160:4,7,9,14 169:22 images 108:5 imagined 44:9 immediately 157:5 163:4 impact 25:2 27:7,10,13,20,21 28:16 34:6,17,22 42:19 44:10 48:18 49:15 50:11,12 51:3,5 53:15,21,22 54:14 65:18 119:6 158:13 impacted 135:14 impacts 35:18 40:12,14 44:12 48:21,22 49:22 50:3,13 51:18</p>	<p>52:6 53:7,8 54:1,2,12 55:3,9,13,21 56:1 58:7 59:20 60:16,18 63:6 72:14 impartial 113:20 impenetrable 93:5 implement 22:17 47:18 51:11 71:7 109:12 118:22 implementation 15:20 23:9 44:8 implemented 23:14 24:2 140:21 157:14 implementing 26:16 40:21 46:22 47:2 48:20 61:17,22 65:6 73:12 implications 71:19 162:15 importance 45:18 important 16:21 18:18 19:2 30:20 31:1 39:15 46:2 48:4 52:1 55:7,13 57:6 79:20 84:17 93:14 124:11 importantly 71:21 imposed 45:13 impressive 106:13 improve 16:5,9 17:20 56:21 62:2,13,18,21 63:11 64:2 70:7 100:3 162:7,14</p>	<p>166:22 improved 95:13 improvement 65:4 93:12 171:2 improvements 25:10 110:7 improving 22:12,14,16 inaudible 12:12,17,19 31:12 32:18 33:12 97:4 123:18 132:18 133:9 135:17,22 136:13,15 137:12,14 139:10,11 141:16 142:12,14 146:12 152:4,9 153:10 154:1 158:14 166:14 172:9 inaudible).gov 91:17 incidents 25:18 include 52:10 59:3 66:10 112:13 included 48:10 163:5 includes 55:9 58:17,22 including 26:20 28:7,13 66:3 112:3,22 113:12 114:9 137:20 income 57:5 incomplete 67:3 incorporated 8:19</p>	<p>59:12 increase 24:9,20 25:21 26:8,12 36:9,17 38:12 65:15 66:21 73:5,14 84:12 114:20 116:5,6 132:3 increased 36:7 37:15 169:7 increases 65:9 increasing 26:12 36:8 increasingly 18:6 35:14 55:6 incremental 54:2 indentify 101:1 independent 9:18 120:5 in-depth 78:16 indicate 49:1 52:16,18 indicated 120:14 indication 126:15 indirect 53:8,10,15,17,22 58:9 indiscernible 68:3 72:21 74:7 78:13 98:5 104:12 106:18 120:5 134:6 individual 69:20 114:2 144:10 individually 48:18 individuals 70:2 indulge 160:12</p>
--	--	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 20

<p>industrial 37:7</p> <p>industries 59:9</p> <p>industry 55:11 58:17 59:9</p> <p>infinite 92:14</p> <p>info 90:6 102:21 103:9,20</p> <p>infomercial 61:19</p> <p>inform 18:21 20:12 124:7</p> <p>informal 71:5 111:12</p> <p>information 3:3,4 14:11,14 55:8,11 61:21 63:10 64:1,2,5,13 65:15 66:10 67:1 70:3,6 72:10 74:9 76:20 77:2,5,9,18,21 78:5,21 82:6 83:14,22 84:6 85:10 87:15 90:1,11,15,20 91:21 92:2,9,11 93:2,9 94:2,16 95:5,9 96:21 97:21 98:13 99:8 100:15 101:11 103:4 104:12,15,16 105:7 107:10,13,15 108:9 111:10,12,16,18 112:15,17,19,20 113:1,4,7,8,9,18 114:3,8,9,15,17, 18,20 115:2,4,7,9 116:1,6,9,12</p>	<p>117:1,16,18,19 118:2,3,9,13,14, 18,20 119:4,13,17,20 120:4,7,8 122:12,17,22 123:2,19 124:5 126:6,8 128:10,13,20 129:5,9,10,17,19 130:11,21 132:1 133:3 138:4,7 139:17 142:5,10,18 145:5,9 147:9,10 151:11 152:22 153:1 165:11,12 166:21 167:12 173:4</p> <p>informational 107:3</p> <p>informative 145:10</p> <p>informed 28:5 40:14 59:19 115:1</p> <p>informing 48:4</p> <p>infractions 160:19</p> <p>infrastructure 23:21 25:5</p> <p>in-house 20:8</p> <p>initial 63:17 149:13</p> <p>initiated 25:15</p> <p>initiative 30:17 84:12</p> <p>initiatives 14:13</p> <p>in-progress 123:7</p> <p>input 14:16 16:8 40:16 41:5 45:14</p>	<p>56:8 59:22 60:1 172:18</p> <p>inputs 54:17,20 55:22</p> <p>inquiry-based 163:21</p> <p>insisted 21:20</p> <p>inspection 1:6 78:22 115:10 160:16 161:11</p> <p>inspections 25:15 26:8,12</p> <p>installed 160:15</p> <p>instead 97:7 99:10</p> <p>instituted 77:13</p> <p>institution 72:7</p> <p>institutions 71:21 72:12,13 114:7</p> <p>instruction 115:18</p> <p>instructions 84:20</p> <p>integrated 48:9</p> <p>integrating 82:2</p> <p>integrity 79:15</p> <p>intelligent 161:9</p> <p>intended 38:11 43:1 46:13 74:9 78:20 110:18</p> <p>intent 27:14,22 42:2 119:15</p> <p>inter 113:11</p> <p>interact 62:21 71:3</p> <p>interacting 63:7</p> <p>interaction 63:5</p> <p>interactions 62:12 63:3,21</p>	<p>interactive 42:10 60:17</p> <p>interest 9:8 15:5 26:4 27:2 29:9 43:22 44:1 61:2 71:13 114:19 115:22 118:11 119:7 123:22 130:9 165:4 167:1</p> <p>interested 22:5 55:1 68:9 142:3 165:2,3 174:13</p> <p>interesting 41:14 158:16 160:20 169:10</p> <p>interests 41:20 109:19</p> <p>interfere 113:19</p> <p>interject 105:14</p> <p>internal 112:21 170:13</p> <p>internally 82:3 109:21 164:8</p> <p>international 19:21 162:15</p> <p>interpretations 115:16</p> <p>interviewing 17:2</p> <p>intragovernment 113:12</p> <p>introduce 6:8 18:11,12 22:2 131:10 167:22</p> <p>introducing 122:15</p> <p>introduction 17:22 22:14 25:12 106:13</p>
--	--	--	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 21

<p>introductory 6:7</p> <p>invasion 113:21</p> <p>investigating 74:16</p> <p>invite 156:16</p> <p>inviting 108:3,7,16</p> <p>involve 142:6</p> <p>involved 27:5 48:6 103:21 165:7</p> <p>Iowa 171:2</p> <p>irreversible 51:10</p> <p>Isabelle 7:20</p> <p>ISB 91:13</p> <p>isn't 66:21 123:9 133:11 134:2,9 166:18</p> <p>ISO's 25:16</p> <p>issue 30:19 34:11 36:19 49:13 50:5 59:5,14 74:1,21 103:13 105:2 109:17 139:5</p> <p>issued 14:4 25:13 28:21 30:5</p> <p>issues 5:6 15:4 19:7 21:9,14 22:8 28:1 31:1 40:8,18,20 41:1,10 43:18 45:11 49:12 51:15,16 54:18 56:4,5 58:19 59:6,22 60:15 63:13,16,17 75:9 92:11 99:17 126:7 127:7 134:5 139:9 168:14,18 169:5,14,18</p>	<p>issuing 69:18 74:5</p> <p>item 72:1 164:7</p> <p>items 121:3</p> <p>iterative 70:8 90:12</p> <p>It'll 153:1</p> <p>it's 14:9 16:21,22 25:21 33:14 34:17 35:12 36:16,22 37:7,22 39:13 41:14 45:2 46:6 52:1,5 53:3,22 57:16 60:6,17 61:20 62:5,19 67:8 68:5,6 69:8 70:8,19 74:5,8 76:22 79:3,18,19,20 80:18,20,21 81:1,15 82:4 83:2,12 85:7,9,11 89:13 90:12 91:1 93:9 95:1,18 96:9,10,11 97:22 98:11 99:15 100:14,15,17 101:22 102:5 103:18 104:15 121:17 123:17 124:8,11 125:11 126:5,17 127:19 128:3,7,8 129:12 130:1,9 131:21 132:16,21,22 133:17 138:17 139:9,22 140:2,10 142:1,3 144:7,16,17 150:4 151:4,18,19</p>	<p>152:4,10,19 157:11 158:7,22 162:11,14 165:11 169:10 171:19</p> <p>I've 20:15 21:6 76:17 78:1 79:5 89:9 150:22</p> <hr/> <p style="text-align: center;">J</p> <hr/> <p>Jack 9:13</p> <p>Jacobs 137:16,20 139:11</p> <p>January 37:20 149:17 151:14 156:22 157:4</p> <p>Jay 6:16</p> <p>Jeff 9:21 104:4</p> <p>JEFFERY 9:21</p> <p>Jeffrey 5:9,10 104:3 174:3,18</p> <p>Jenkins 8:20</p> <p>Jhee 23:8 160:3 165:2</p> <p>Jill 10:5</p> <p>Jimmy 47:4</p> <p>job 4:7 59:10 82:2 106:22</p> <p>John 2:9 7:13 12:15 20:22 33:4,12,13 38:16 39:16 48:12 73:21 74:11</p> <p>join 62:6,7,14 65:22 156:17 166:12</p> <p>joined 76:18</p> <p>joining 105:17</p>	<p>joins 105:22</p> <p>jointly 45:7</p> <p>Jones 10:22</p> <p>Jordan 11:19</p> <p>Juba 10:7</p> <p>judge 29:1</p> <p>judged 80:7</p> <p>judge's 29:5 32:6</p> <p>July 164:15</p> <p>jumped 100:2</p> <p>jumping 91:15</p> <p>jurisdiction 56:5</p> <p>Justice 32:11</p> <p>justification 119:9</p> <p>Justin 9:15</p> <hr/> <p style="text-align: center;">K</p> <hr/> <p>Karen 10:18 11:17,22</p> <p>Keith 31:11,12 32:1 107:2</p> <p>key 15:2 20:5 26:18 40:8 52:1 86:12 89:7 102:10 103:14 108:21 162:5</p> <p>kicked 161:19</p> <p>kids 106:4</p> <p>kinds 21:9 63:8,21 67:19 92:6,9 107:4 141:6</p> <hr/> <p style="text-align: center;">L</p> <hr/> <p>ladies 147:21</p> <p>laid 64:17</p> <p>land 49:15 53:16</p>
--	---	--	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 22

<p>language 71:13 92:22 141:18</p> <p>large 35:14 52:20 71:16,22</p> <p>largely 47:9</p> <p>larger 57:21 88:4</p> <p>Larry 10:2 69:7</p> <p>last 12:21 14:12 17:1 18:4,10 20:7,18 21:17 22:10,11,18,20 23:10 27:11 28:11 40:18 54:1 62:1 80:14 92:16 98:20 105:12 106:21 135:5 159:15 160:2,8,11 163:16,17 164:7</p> <p>lastly 59:1</p> <p>late 13:22 164:17</p> <p>later 6:6 55:5 104:17 110:1 113:10 152:16 171:21</p> <p>latest 4:13 79:17</p> <p>Laughter 9:4 12:13 17:5,10,13 21:21 32:21 46:11 61:9 75:7 89:12 92:17 97:5 99:2,4 104:5 105:20 106:6,16 109:8 112:10 123:10,12 125:13,16 129:11 149:1 152:5 160:1 166:5,13,15 168:2,3,5</p>	<p>171:5,8</p> <p>launch 149:17 151:14,15 156:22 157:1</p> <p>law 42:1 45:21 47:10 79:12 113:2,16,17,22 117:20 134:8</p> <p>lawsuit 28:20 30:4</p> <p>layer 99:11</p> <p>layers 130:22</p> <p>lays 30:8</p> <p>lead 30:19 160:22</p> <p>leading 23:8 76:6,13</p> <p>leads 163:22</p> <p>Lean 26:22 170:19</p> <p>learn 77:22 96:13 106:19 116:18 166:21</p> <p>learned 163:6</p> <p>least 5:20 41:5 96:10 101:19 129:22 142:1 166:20 167:4</p> <p>leave 87:4 155:11 172:11</p> <p>leaves 23:12</p> <p>led 30:18 37:22 163:12</p> <p>Lee 3:7 12:4,18 148:5,13,14 158:9 159:7</p> <p>legal 115:16</p> <p>legally 37:17</p> <p>lengthy 64:18</p> <p>let's 6:4 31:16</p>	<p>32:17 38:19 40:22 41:6 51:12 58:11 75:17 78:19 93:4</p> <p>letter 119:15 123:4 126:20 145:20</p> <p>letters 74:6,22</p> <p>letting 123:21</p> <p>level 20:21 102:20 140:22 155:16</p> <p>levels 130:15</p> <p>liaison 148:16</p> <p>libraries 37:9</p> <p>licensees 117:22</p> <p>life 114:1</p> <p>light 44:17 106:14,17 155:21</p> <p>likelihood 44:11 49:7</p> <p>likely 24:14</p> <p>limit 57:11,18,19</p> <p>limitation 62:13</p> <p>limited 27:4 45:8 49:7 71:20</p> <p>limits 57:19</p> <p>Linda 7:4 12:3</p> <p>line 72:1 114:16</p> <p>lines 100:11 106:4</p> <p>link 82:18 84:16 85:5 90:22 96:1 103:17 151:10</p> <p>linked 95:17</p> <p>linking 81:7</p> <p>links 90:9,16 94:4 96:2 97:22</p>	<p>107:22</p> <p>Lisa 7:9</p> <p>list 15:14 49:12 101:20 138:6</p> <p>listed 56:19 77:9 79:5 81:10 90:2 120:21,22 121:9 145:19 147:12 163:16,19 164:3,5</p> <p>listening 16:22</p> <p>listing 145:15</p> <p>litigated 129:19</p> <p>litigation 27:5,6,15 29:8 30:7,12 35:12 124:21 134:15 138:20 140:2</p> <p>little 4:22 19:5 22:10 31:7 35:22 49:20 61:8 64:11 75:10 78:9,17 79:21 80:13 84:4 85:1,12 86:9,10 93:5 95:10 96:2 97:16 107:14 108:7,11,15,16 109:3 143:13 148:8 150:4 156:2 161:5</p> <p>live 80:18 81:14,15 82:6 106:3 116:17</p> <p>lives 82:13</p> <p>load 130:20</p> <p>loading 94:10</p> <p>local 111:22 112:4</p> <p>located 165:9</p> <p>location 157:9,12</p>
---	---	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 23

<p>158:8 165:5 locations 36:11 37:3 locked 152:19 log 98:15 129:16 146:8,21 147:4,5,7 154:3 159:1 logged 75:15 logistical 70:14,21 logistically 4:10 logs 146:5 long 17:12 18:5 21:6 70:19 74:1 83:20 103:10 127:10 longer 36:13 91:5 100:17 109:4 110:9 lookout 82:5 157:21 loops 90:8,10 LOP 25:18 lost 123:11 lot 5:5 18:13 19:12 30:16 36:18 74:16 81:17 88:19 89:20 91:12 92:2,21 93:9 94:7 97:21 101:7 103:13,20 106:21 108:3,4,12 127:20 141:17 149:18 150:17 162:5,10,18 163:6,7 lots 92:2 110:4</p>	<p>love 46:6 106:2 loved 82:16 low 104:8 108:22 LPA 84:7 lumped 19:13 lunch 4:11,15 16:10,12 75:16 84:8 110:9,12,13,15,1 9 Lunches 4:14 lunchtime 22:3 <hr/> M <hr/> machine-readable 84:13 main 6:5 42:4 43:15 48:3 97:17 103:5 mainly 39:19 maintain 73:5,13 96:13 161:8 maintained 79:8 83:13 126:6 major 160:15 MALE 75:6 91:10 92:18 104:6 125:5 127:9 141:10,16 142:7,22 143:5,11 153:5,13 Malloy 12:5 management 3:9 16:15 21:11,13 22:18 25:16 31:21 80:9 161:14 162:7,14</p>	<p>manager 3:4 111:10 mandate 43:8 mandated 47:16 56:6 141:5 mandatory 47:5,11 maneuver 116:18 manipulate 84:16 manner 34:7 manually 155:11 158:3 manuals 115:18,19 map 101:14,18 maps 103:14 114:9 March 27:11 30:9 Margaret 10:22 MARGRET 10:22 Maria 8:18 marked 24:19 marketed 57:13 58:1 marketing 56:11 Maryland 1:12 massage 84:16 material 102:5 113:12 matter 83:3 131:6 158:8 matters 130:7 maximize 72:20 may 4:21 5:2,4 6:5 14:15 28:8 33:9 42:21 49:10,13,15</p>	<p>50:14 52:16,17 53:9,12 54:7 55:12,17 56:3,5,8 57:14 66:10 72:4,5,8 81:4 84:18 86:15 87:5 96:10 98:10,18 100:8 101:21 105:14 107:19 141:14 142:17 143:2 145:10 155:1 164:21 170:20 maybe 57:16 79:22 92:12 93:12 99:10 100:12 101:21 107:22 131:7 135:9 138:4 142:19 144:1 165:17 167:15 171:10 MC 4:6 McCammon 11:2 McDermott 9:6 mean 13:9 48:21 50:19 52:14 70:16 72:6 84:14 100:16 109:6 117:20 124:3 125:19 127:18 128:14,19,20 147:2 157:4 meaning 63:14 means 4:7 30:2 42:8 43:16 48:6 76:13 84:14 114:16 169:22 meant 49:6 measure 65:4 81:19</p>
--	--	---	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 24

<p>measures 71:6 81:6</p> <p>mechanism 65:14 72:11 74:22</p> <p>mechanisms 63:3,13 64:4,7,15,19 65:6 71:14 72:19 76:20</p> <p>media 77:12 147:5</p> <p>meet 34:18 52:2</p> <p>meeting 1:8 4:4 13:18 14:1,10,11 15:1 16:4 18:4 20:18 21:20 35:16 69:20 79:13 166:20 172:17 173:10 174:4</p> <p>meetings 70:1 78:2 172:15</p> <p>meets 35:19</p> <p>MEGS 85:11</p> <p>Mel 71:12</p> <p>member 154:4</p> <p>members 19:4 22:3 37:21 63:4</p> <p>Mendelsohn 11:15,16</p> <p>mention 5:8 30:4 54:9 77:11 78:8 83:18 84:9 85:6 165:15 170:10,18 171:2</p> <p>mentioned 16:11 23:20 29:14 31:13 48:12 74:3 76:17 82:11 91:14 95:22</p>	<p>101:20 102:8,9 122:1 137:17 153:5 154:13 158:13 168:13 169:6 170:11</p> <p>message 95:14</p> <p>messages 95:13,17</p> <p>met 18:10</p> <p>Metabolix 8:10 93:19 122:20</p> <p>Metgin 8:22</p> <p>methods 57:1 113:22</p> <p>Meyers 9:15</p> <p>mic 5:17 69:5</p> <p>Michael 2:6 6:12 10:1 11:15 76:17 102:19 170:10</p> <p>Mick 10:3</p> <p>Mickle 174:3,18</p> <p>micro 132:14</p> <p>microphone 5:15 6:6,10 61:12,13 124:18 125:5</p> <p>mid-2000 36:21</p> <p>mid-December 81:15</p> <p>middle 92:17</p> <p>midst 5:3</p> <p>Midway 117:4</p> <p>midways 145:10</p> <p>migrated 105:1</p> <p>Mike 4:11 6:7,12 10:1 11:15 13:5 31:12 32:4,15 35:13 37:19 52:22 80:4 81:22</p>	<p>102:19 167:2,10 168:7 170:22 171:4 172:1</p> <p>Miller 6:16</p> <p>million 24:10</p> <p>mind 5:11 69:9 122:14 172:11</p> <p>minimize 161:2 165:18</p> <p>minimized 49:1</p> <p>minor 54:7</p> <p>minus 147:8</p> <p>minutes 15:5 33:6 75:10 87:17 88:11</p> <p>minutiae 105:10</p> <p>mirror 58:14</p> <p>miss 12:16</p> <p>mission 47:14 162:2,18</p> <p>mistakes 103:16</p> <p>mitigations 49:3</p> <p>mobile 99:15,16</p> <p>Moderator 2:2 3:2</p> <p>modern 17:4</p> <p>module 149:3,11 150:3,20,22 151:7 157:8</p> <p>modules 153:2</p> <p>mom 109:6</p> <p>moment 75:11 148:4</p> <p>moments 160:12</p> <p>Monday 28:17 32:13 105:16 106:1,21</p>	<p>money 109:19 154:10</p> <p>monitor 101:1</p> <p>monitoring 149:5</p> <p>Monsanto 7:8 8:15,17,21 10:1,10 70:12 100:1 102:19 137:17</p> <p>month 27:14 28:11 89:18 135:2</p> <p>months 66:6 67:7 81:5 167:5 171:22</p> <p>morning 2:4 4:3 8:2 12:6 13:16,21 15:19 24:4 33:4,14 76:5 81:22 110:12 121:17 135:9 159:21 167:2,10 168:13 170:17 171:3</p> <p>morning's 19:6</p> <p>mostly 160:9</p> <p>motivation 41:11</p> <p>move 5:3 32:18 38:5,19 50:7 61:2 92:14 97:20 171:18</p> <p>moved 21:1</p> <p>movement 171:21</p> <p>moving 98:15 171:12</p> <p>Mullins 9:16</p> <p>multinationals 130:17</p> <p>multiple 84:6 96:16 99:11</p>
--	--	---	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 25

138:1,20,22 153:9 158:5 multiplicity 52:17 multiyear 157:21 myself 13:21 39:3 106:19 <hr/> <p style="text-align: center;">N</p> <hr/> nailing 110:3 narrow 102:15 narrowly 156:9 Natalie 6:18 89:15 national 2:8 9:1 15:20 41:13 nationals 111:21 natural 43:14 56:11 nature 94:11 126:4 Navigability 93:13 navigable 86:9 navigate 16:5 85:16 96:10 98:1 99:6 103:12 navigation 87:7,8 nearly 36:17 necessarily 60:5 101:17 104:21 125:21 126:3 129:4 necessary 51:14 64:5 neither 174:8 Nelson 9:16 NEPA 2:10,11,13 15:22 18:19,21,22 19:7	20:12 24:2,3,5 26:16 33:7,11,17,19,21 ,22 34:1,10,13,20 35:3,4,10,13,16, 21 36:1,4,6 37:16,19,21,22 38:2,4,6,8,12,22 39:2,4,8,9,11,12, 18 40:1,4,9,12,22 41:7,22 42:5,17,22 43:8,20 44:4,13 45:2,4,16 46:3,13,19,22 47:8,18 48:8,10,12 50:16 55:21 56:15,16 60:5 61:4,6,16 62:3,13,16,18 63:11 64:2,6,14,16,17 65:5,12,17,20 66:19 67:11 68:5,10 69:1 75:9 102:3 169:7 NEPA-related 33:8 63:13 NEPA's 35:10 42:19 46:9 Nesbitt 2:2 3:2 4:2,4 10:11 12:12,16,20 13:4 31:7 32:3,14,17 33:3 38:15,19 61:1 68:18,21 69:4 70:10 71:8,10 72:21 73:17,19 74:11 75:5,8,21 76:3,10,12 88:13	89:14 91:8 93:17 99:20 102:18 105:12 110:11,22 111:3 120:11 122:14 125:4,6,14 127:8 131:10 132:14,16,18 133:9,11 134:21 135:17 137:13,15 144:12 146:4,7 147:17,19 148:4,8 152:3 153:4 154:12 158:9,11 159:4,6,9,14 166:1,4,6,9,11 167:20 168:3,4,6 170:7 172:1,6,8 173:5 nevertheless 47:22 newer 74:7 160:6 164:19 newest 25:16 newly 38:22 news 6:21 17:7 32:6 82:18 94:2 165:11,12 nice 39:8 95:16 Nicholas 42:4 Nicole 10:7 11:18 night 17:1 nine 81:9 135:9 Nixon 42:2 47:1 noise 98:16 non 112:16 noncompliance 161:1	nonregulated 29:11 34:21 39:21 74:8 nor 34:3 174:9,13 normally 169:12 note 41:15 50:3 55:15 104:10 160:20 notes 45:5 nothing 79:6 103:12 133:16 notice 27:22 68:14 70:18 119:1,22 120:3 134:12,14 144:1 163:9 noticed 71:13 notices 79:2 102:3 notification 95:1 100:7 101:2 150:12,19 153:20,22 154:17 155:8 notifications 25:14 34:11,18 36:2,6,10,13,20 37:6 78:22 84:22 89:21 94:12 96:16 104:9 116:13 123:19 149:8 150:1 152:22 153:10 154:6 notify 128:2,8 notion 29:9,14 novel 49:18 nuts 22:5 26:21 Nygaard 7:4 <hr/> <p style="text-align: center;">O</p> <hr/>
---	---	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 26

<p>Obama 14:4 80:3 114:11</p> <p>objection 120:4</p> <p>objective 63:1</p> <p>objectives 42:4 63:2</p> <p>obtain 111:19 117:17 128:18</p> <p>obtained 112:12 118:9</p> <p>obviously 5:22 78:20 79:11 93:13</p> <p>occur 53:9 54:8 97:22</p> <p>o'clock 159:12</p> <p>October 23:2</p> <p>offer 149:19</p> <p>offered 167:10</p> <p>office 3:4 11:6 21:18 23:14 30:18 31:20 45:5 111:5,10 112:3 116:10 120:15 122:18 123:8 138:10</p> <p>officer 23:15 131:13 174:3</p> <p>offices 115:11 117:11 144:11</p> <p>official 96:4 159:15</p> <p>officially 23:3,13 68:17</p> <p>officials 46:14 48:4</p> <p>OGC 169:7,11</p> <p>oh 12:17 46:10 80:14 88:1 98:20</p>	<p>112:9 122:16 128:21 133:21 139:1 148:21 171:7</p> <p>OIG 23:10,12,18</p> <p>oil 57:16,17</p> <p>Okamuro 9:13</p> <p>okay 12:16,20,21 13:4,7,8,12,16 31:9,16 32:17 33:12 38:15,19 73:17 75:8 76:3 91:8 93:17 97:6 99:20 104:6 105:12 111:9 121:5,22 125:6,15 133:3 136:14 137:10,13 139:10,12 140:17 143:5,11,15 144:19 147:14,19 148:22 152:12 153:3 155:5 159:6 166:6,8 169:3 171:4 172:8 173:5</p> <p>old 41:15 100:10,17 101:8 136:19 141:4</p> <p>older 102:7</p> <p>old-timers 20:17</p> <p>OMB 81:7 82:7</p> <p>onboard 18:9</p> <p>one-quarter 20:19</p> <p>ones 47:15 52:10 90:1 164:8</p> <p>One's 164:20</p>	<p>one-to-one 39:7</p> <p>ongoing 79:16</p> <p>online 149:3 150:16</p> <p>onto 116:20</p> <p>open 14:4 23:10,16,18 84:11 96:17 110:16 165:1 167:19</p> <p>operating 26:17 38:14 114:5</p> <p>operational 164:7</p> <p>operations 3:11 19:8,16 23:7 31:19 159:17</p> <p>opinion 74:1,6,21</p> <p>opinions 113:13 115:15</p> <p>opportunities 16:4 41:5 43:14 62:1 69:12</p> <p>opportunity 4:19 5:21 40:15 44:5 45:20 86:8 119:19 124:10,14,15 166:19 167:11</p> <p>opposed 78:6 82:15</p> <p>option 29:21 55:18</p> <p>options 52:8</p> <p>order 4:15,20 14:6,9 16:11 27:7 32:6 45:21 47:6 62:21 98:8 110:15 112:19 117:21 120:1 124:9,12,13</p>	<p>ordered 27:19 110:13</p> <p>orders 4:13 14:2 60:8</p> <p>org 91:2</p> <p>organic 30:21 56:11 57:2 58:18</p> <p>organism 49:6</p> <p>organisms 18:1 22:14 25:13 162:9,17</p> <p>organization 5:18 21:14 23:22 69:5 72:7 90:5,21 101:21 102:2 104:20 105:4,11 154:7 155:7 156:12,14,17,18 162:12 165:5</p> <p>organizational 18:3,8 20:6,15 22:4 153:16 154:14 157:17 158:20</p> <p>organizations 72:4 111:21</p> <p>organization's 162:7</p> <p>organized 101:21 103:18</p> <p>origins 41:7</p> <p>Orr 7:11</p> <p>others 37:11 39:3 80:2 171:16</p> <p>other's 155:7 156:15</p> <p>otherwise 38:16 75:17 86:16 174:13</p>
---	---	--	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 27

<p>ought 126:12</p> <p>ourselves 53:4 91:14 161:18 170:18</p> <p>outcome 174:14</p> <p>outcomes 65:11 81:8</p> <p>outlined 171:17</p> <p>outlines 81:5</p> <p>output 100:9</p> <p>outreach 2:16 76:13</p> <p>outside 38:3</p> <p>outweighed 43:5</p> <p>overall 24:9 62:19 65:16</p> <p>overhead 71:22</p> <p>oversee 43:17</p> <p>overseeing 18:20 26:14 45:7</p> <p>oversees 45:2</p> <p>oversight 28:15 45:9 117:22</p> <p>overturned 27:17</p> <p>overview 3:3 33:20 77:5 111:11,14 165:14</p> <p>owner 153:19</p> <hr/> <p style="text-align: center;">P</p> <hr/> <p>packet 14:20</p> <p>page 2:2 90:18 92:16,17 93:5 95:22 96:1 103:19 117:3,4 144:21</p>	<p>145:3,11,13,18</p> <p>pages 84:2 90:17 92:15 116:11</p> <p>paper 112:13 149:10</p> <p>paperwork 46:10</p> <p>Parham 9:10</p> <p>parking 5:5</p> <p>partial 28:14 29:9,14,15,20,22 30:2 52:22</p> <p>participant 164:1,11</p> <p>participants 62:10,14 68:16 69:20 71:1 160:6 161:19 163:5 164:6,16,19 165:19</p> <p>participate 41:5 66:16 67:15 72:8,9 73:10 162:13</p> <p>participation 25:22 63:19</p> <p>participatory 14:8 31:2</p> <p>particular 90:4 92:12 101:2,3 103:19</p> <p>particularly 36:8 43:22 103:6</p> <p>parties 55:1 142:9 174:10,13</p> <p>partner 124:11</p> <p>partnering 118:15</p> <p>partnerships 44:7</p> <p>passing 5:16 6:9</p>	<p>past 23:17 25:13 27:9 35:8 36:18 54:3 64:9 74:22 79:14 86:4 91:1 94:20 129:22 131:17 134:7 148:9 150:5,6 156:1 165:14,16</p> <p>path 160:22 161:3</p> <p>pathway 51:14</p> <p>Paula 7:15</p> <p>Pauline 12:2</p> <p>Pause 6:11 9:12 13:13,15 32:16 38:18 69:3 71:9,11 73:1,18 76:2 88:8 97:2 98:16 111:2,7 112:7 120:10 123:12 144:15 146:1,10,15,20 147:16,18,22 148:3,7,12 152:1 158:10 159:5 160:14 166:3 172:7</p> <p>paying 74:7</p> <p>PCP 76:8</p> <p>peaked 36:21</p> <p>pen 86:19</p> <p>pending 132:10 135:1</p> <p>people 13:20 15:5 16:6 18:11 27:3 30:1 42:9 66:7 68:8 73:15 83:2,8,17,22 84:10 85:8,9,15 86:14 89:10 90:22 96:13 99:9</p>	<p>100:19 108:10 124:14 129:1,12,16 130:8 133:12 140:8 141:7 142:3,18 151:1 154:15 155:6,16 156:17 161:7 169:3</p> <p>per 26:9 35:6 97:10</p> <p>perfectly 87:2</p> <p>perform 26:8 57:15</p> <p>performance 80:9 81:3,10</p> <p>performance.gov 78:11 80:18 81:14 82:5</p> <p>perfunctory 96:6</p> <p>perhaps 39:14 71:21 83:7 94:10,13 96:2</p> <p>period 24:15 27:10 28:17 70:17,19,20 119:8 149:13</p> <p>permit 25:15 29:1 30:5 49:4 95:1,17 98:3,4,8 100:6 101:2 150:6,8,9,12 153:19 155:1,3 156:6 158:5</p> <p>permits 25:14 28:21 34:11,20 35:6,9 36:2,6,10,20 37:5 66:4 78:22 84:22 89:20 92:8 93:13 94:12</p>
---	--	--	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 28

<p>96:20,21 98:3 103:6 104:10 116:13 149:7 152:22 154:5 155:7 156:6 157:22 158:13,14</p> <p>permitting 150:1,18 151:8 158:21 170:13</p> <p>person 54:5 78:3 88:2,4 94:17 105:16 111:20 113:20 118:9 128:17 153:8,9,17,18,21 155:2,8,9,10 156:13</p> <p>personnel 21:13 112:22</p> <p>perspective 39:9 43:20</p> <p>petition 23:20 24:11 26:15 39:20 50:21 51:20 55:4,20 62:8 66:1,4,12 67:3,7,8,13,14,2 2 68:2,6 69:10 91:4 93:11 100:7 103:19 127:2,17 130:4 131:20 132:20 133:2 136:6,10,11,20 137:4 138:2,8 170:17 171:3</p> <p>petitioner 54:20 57:6 123:21 129:3</p> <p>petitioners 57:10 64:8</p>	<p>petitioning 170:15</p> <p>petitions 25:6 29:11 34:12,21 35:4 66:2 78:21 84:22 89:20 100:16 103:6,7,8 104:10 116:13 123:19 131:17 132:4,10 133:18 135:2,19</p> <p>ph 8:7,22 9:17 10:3,21 11:9,14,17 12:7,10 35:19 42:4 47:22 49:18 70:13 71:12 84:7 104:16 137:16</p> <p>pharmaceutical 37:7</p> <p>phenotypes 96:19</p> <p>phone 95:7 101:20 117:1</p> <p>photos 112:14</p> <p>physical 58:18 59:21 114:1</p> <p>pick 31:11 167:11</p> <p>pictures 87:4</p> <p>piece 78:11 92:22</p> <p>pilot 2:13 15:22 24:3 26:16 33:19 38:6 61:6,16,19,20 62:4,7,8,9,10,15 64:10 65:3,22 66:1,6,7,11 67:15 68:16,22 69:18 70:4,9,15,20,22 72:3 73:10 161:18,22 163:3</p>	<p>pinch 160:5</p> <p>Pioneer 89:16</p> <p>placed 115:14 121:2</p> <p>places 151:8</p> <p>plaintiffs 29:2 30:8</p> <p>plan 33:19 67:4 73:5 85:17,21 86:2 118:7 168:22 171:14</p> <p>planned 16:18 164:20</p> <p>planning 40:1 42:14 43:19 56:2 144:8</p> <p>plans 38:1 81:19</p> <p>plant 1:6 34:1,3 58:20 68:2</p> <p>planting 28:14,22 149:5 150:10 153:21 157:10,12</p> <p>plant-pest 36:4</p> <p>plants 29:3 37:7,10 81:13</p> <p>play 33:21</p> <p>please 4:12 5:17 35:5 76:4 88:14 110:22 162:2 172:11</p> <p>pleased 22:17</p> <p>plenty 69:1</p> <p>plug 82:10</p> <p>podium 13:5 61:8</p> <p>point 5:15 20:17 30:10 37:14 46:2 52:19 61:13</p>	<p>66:20 68:11 95:4 120:13 124:2 133:2,6,15 142:4,7 150:7 153:6 163:20,22</p> <p>pointing 87:21</p> <p>points 6:5 35:2 89:7 108:21 163:18</p> <p>polices 140:11</p> <p>policies 44:22 45:12 115:16,17 140:7</p> <p>policy 2:8,17 12:1 15:21 19:18 20:3,4 21:1,5,7,9 31:1,17 41:14 43:12 44:18 76:8,18 120:22 122:3 140:5,18,22 143:17 163:11</p> <p>pop 95:3 98:10 151:11</p> <p>popular 141:6</p> <p>population 85:10</p> <p>portion 35:15 162:13 165:10</p> <p>portions 126:21</p> <p>position 18:5 119:7</p> <p>positions 18:10</p> <p>Positives 103:18</p> <p>possibilities 44:11</p> <p>possibility 45:16 50:1 53:1 54:10</p> <p>possible 4:8,12 49:21 51:10,18 55:13 56:1 57:12</p>
---	--	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 29

<p>59:20 60:16 101:16 108:13 165:7 possibly 74:22 99:8 155:22 post 114:15,16,17 116:1 121:20,21 122:10,13 125:20 137:8 138:12,13,15 139:3,7 143:6 144:8 145:9 151:3 posted 115:5 116:19 117:12 121:4,13 123:15 128:7 131:20 132:5,13 133:18 135:8 136:21 144:7 145:13,16,17 152:20 posting 115:11 117:9 125:8 135:20 potential 34:5 40:12,14 44:10 45:18 49:14 54:14 55:9 60:18 63:5 71:18 potentially 56:13 57:22 157:21 power 106:4 powerful 80:8 PPQ 158:14 159:2 practicable 42:8 practices 101:13 112:22 predecision 113:13</p>	<p>preface 89:8 prefer 52:18 75:16 preliminary 26:18 69:19 preparation 27:20 28:4 68:10 prepare 20:11 27:7 35:5 38:4 68:4 70:2 73:8,14 prepared 15:13 33:18 34:20 35:9 39:20 50:14 66:18 67:4 74:21 114:5 preparing 24:5 65:16 present 37:4 52:5 53:2 54:3 56:14 107:4 presentable 86:10 presentation 4:21 19:6 33:4,10 38:20 48:13 60:10 69:8 76:6 78:15 111:5 113:10 116:17 148:5 presentations 107:4 presented 58:5 presenter 15:13 presenting 40:20 preserving 43:13 President 14:4 45:6 80:7 112:3 114:11 141:19 President's 80:22</p>	<p>pressure 169:17 presumably 59:18 presume 120:3 presumption 129:18 pretty 77:2 92:10 104:8,19 151:21 prevent 42:5 50:3 previous 16:4 78:1 previously 19:19 primarily 4:6 35:4 42:20 93:20 principle 43:8 principles 161:13 prior 18:22 19:12 24:16 132:4,11 136:5 157:18 priorities 14:12 15:3 17:19 25:20 27:1 80:12,17 81:2 prioritized 93:2 priority 15:2 23:17 82:1 171:19 privacy 113:21 129:18 147:8 private 112:5 161:15 privileged 85:20 113:12 118:10 proactive 143:19 proactively 114:15,16 115:8 probably 5:13 53:4 66:21 78:11 79:6 82:20 85:9</p>	<p>94:7 101:9 150:17 170:1 problem 127:14 153:17 155:13 procedural 43:8 47:7 156:2 procedure 34:8 120:22 procedures 26:17 47:17 48:17,20 49:2 164:7,8 proceed 169:1 proceeding 113:19 proceeds 50:20 process 2:10 16:14 17:21 22:13 23:20 24:8,11 25:10,16 26:15,19,21 28:6,9 39:2,8,12,14 40:5,22 42:10 43:21 44:2 46:13,20 51:12,13 60:11,12,13,17 62:3,13,22 63:11,14,18,22 65:2,21 66:8 67:13,18 68:12 69:1,13,15 70:5,6,9 81:18 90:12 118:8 119:1,22 124:3,11 127:5 130:7 132:22 134:5 142:6,16 149:3 154:7 158:4,21 164:2 170:13,15,17 171:1,3,12</p>
---	---	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 30

<p>processes 61:22 167:1</p> <p>procurement 21:13</p> <p>produce 38:7 48:15 50:10</p> <p>produced 46:4</p> <p>producers 57:17</p> <p>producing 46:19 55:19</p> <p>product 49:17 53:15,17 54:22 55:2,13 57:12,15,16,22 113:15 133:1</p> <p>production 57:2 58:16 150:15</p> <p>productivity 56:22</p> <p>products 39:7 40:11 83:15</p> <p>program 2:9,17 3:11 11:6 12:1 17:16,17,20 18:5 19:8,16,22 21:3,5,7 22:12,20,21 24:9,21 25:22 26:2 33:6 56:12 61:6 62:6 71:1,3 76:8 81:12 115:11 117:11 126:3 127:14,15 144:11 148:15 158:18 159:3,17 160:4 161:12,17,20 162:1,11,13 163:11,14,19 167:8</p> <p>Programmatically</p>	<p>17:19</p> <p>programs 2:16 18:18 19:18 21:1,12 23:7 31:18,21 38:10 44:16,20 145:9,15 158:19 163:12 165:19</p> <p>progress 23:19 24:17 63:9 81:6 168:11</p> <p>progressed 47:4</p> <p>project 2:13 3:4 16:1 26:16 33:19 38:6 61:16,19,20 62:4,7,8,9,11,15 64:10 65:3,22 66:1,6,11 67:15 68:16 69:18 70:4,15,21,22 72:3,16 111:9 163:3 171:15</p> <p>projection 149:16</p> <p>promoting 80:12</p> <p>prompted 167:15</p> <p>proper 42:13</p> <p>property 21:13</p> <p>proposal 52:6</p> <p>propose 45:16</p> <p>proposed 50:13 51:5,7,9,11 54:13 58:7 168:19</p> <p>proposing 45:17</p> <p>proprietary 124:5,10 126:8 134:18 143:9</p> <p>propriety 142:18 143:9</p>	<p>protect 46:16 56:20 112:17 124:13 126:7</p> <p>protected 119:5</p> <p>protection 2:12,14 11:16 34:1,3 38:21 43:18 61:4</p> <p>protects 35:19 118:5,6,8,11,14</p> <p>proteins 37:9</p> <p>proud 25:17</p> <p>provide 14:14 16:6,14 40:16 41:2 46:17 49:6 56:8 57:3 84:14 117:19 118:12 119:2,8 147:8 162:6,20,21 167:11 172:19</p> <p>provided 24:20 55:17 84:6</p> <p>provides 43:12,16 45:19 50:9 51:2,8 82:22 83:13 115:1 116:4</p> <p>providing 40:10 53:21,22 55:7</p> <p>public 1:8 9:8 20:10 24:5 28:1,12 29:21 31:1 40:16 43:4 44:1 46:14 48:5,6 49:18 50:9 58:22 59:7,8,22 60:21 70:17 74:10 78:21 79:4 80:19 84:12,21 103:7 115:2,3,6,10,20, 22 116:4 123:22</p>	<p>128:8 130:16,22 131:20 132:5 133:19 142:6 145:10 167:9 173:10</p> <p>publicly 34:7 45:20 131:3 171:17</p> <p>public's 111:18</p> <p>publish 20:11 22:22 27:9,14,22 59:15</p> <p>published 5:12 23:3 28:11 29:16 68:14 131:21 132:11,19 136:5,11 163:17</p> <p>publishing 27:13</p> <p>pull 78:6 82:15</p> <p>purpose 14:10 44:19 46:9,18 52:2 56:16,19 57:5 91:21 92:4 93:14 114:22</p> <p>purposes 48:3 56:20 142:8</p> <p>pursing 45:12</p> <p>push 78:5 82:14 95:13,14</p> <p>pushed 82:18</p> <p>puts 18:4</p> <p>putting 153:6</p> <p>puzzle 52:11</p> <hr/> <p style="text-align: center;">Q</p> <hr/> <p>Q-and-A 166:12</p> <p>quality 3:9 16:15 22:18 25:16 38:8,12 44:4,14</p>
---	--	---	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 31

<p>45:5 62:18 65:5,13 103:16 161:14 quarter 97:10 121:11 135:5 quarterly 121:20,21 query 82:20 question 3:13 31:10 32:13 53:3 69:9 70:12 73:3 74:3 83:7 87:13 90:2 93:21 94:7 97:8 100:20 107:5,6 109:22 120:9 121:8,18 122:19 125:4 127:8 129:21 139:13 152:6 153:4 156:21 158:16 170:9 172:6,9 questions 5:2 14:15 15:6,8,10,12,14 16:16 22:7 31:5,8 32:3,14 33:9 38:16 68:20,22 69:2 70:10 71:8 73:17 75:5,9 82:22 83:1,4,5 86:20,21 87:12,15 88:10 98:14 101:4 111:13 120:11 127:20 130:21 134:20,21 137:13 144:12 146:4 147:17 151:9,22 154:12 158:9 160:7</p>	<p>163:22 166:1 167:12,16,20 168:6 170:7 172:1,3,5 quick 91:1 97:21 165:13 quickly 4:22 50:7 77:12 78:8 84:9 92:22 93:6 105:15 115:1 quite 20:16 25:7 42:18 47:22 70:20 74:1 89:22 90:14 102:20 131:9 140:5 quote 42:15 80:3</p> <hr/> <p style="text-align: center;">R</p> <hr/> <p>rabbit 101:17 Rachel 11:5 radio 17:1,2 116:20 145:1 Rain 11:17 raise 21:5,10 100:22 167:16 raised 49:19 101:6 169:10 range 51:18 62:9 83:3 102:20 rate 26:13 71:20 104:5,7 rather 39:17 42:22 53:22 64:18 110:1 171:20 rating 85:7 rationale 168:18 Ratzow 11:22 Raul 9:17</p>	<p>raw 85:6 Ray 7:8 70:11 99:22 123:18 Ray's 141:11 reach 42:3 reached 110:12 reaching 41:13 readily 107:19 reading 78:14 84:1,5 114:21,22 115:12,13,14 116:14,15,17 117:6,12 121:2,6 136:12,21 137:20 145:7,8 readouts 6:2 ready 27:18 28:10 88:14,15 152:10,19 161:18 real 35:11 132:2 134:17 realistic 170:1 realize 60:3 realized 39:5 really 13:21 16:7,21 17:15 22:5 25:6 37:16 41:1,12,18 42:4,10 45:9 46:6,20 49:3 52:13 53:3 58:1 60:6,16 61:19 62:15,19 65:4,7 69:17 70:7 72:3,16 77:11 78:7,8 80:16 81:17 82:1 84:9 86:8 88:18 89:9</p>	<p>91:21 93:10 96:20 101:14 102:11 105:4,15,21 106:9 108:21,22 109:17,22 110:2 124:13 134:17,18 140:7 143:18 148:17 152:13 155:14 161:2 162:10 170:1 realm 55:14 reason 47:16 51:2 57:18 86:6 90:3 97:18 131:19 168:18 reasonable 19:15 48:7 52:10 59:18 119:8 reasonably 53:13 54:4 reasons 35:11 41:8 89:19 90:2 92:7 97:19 103:5 169:15 reassign 155:12 Rebecca 2:14 12:20 13:2,3 33:18 38:9 40:19 55:16 61:3 68:18,22 73:3 recall 170:16 receive 54:20 55:22 139:17 received 25:16 37:22 106:8 114:17 116:8 recent 36:22 recently 37:8</p>
---	--	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 32

<p>50:17 76:18 94:10,13 140:5 147:3 recess 24:17 recognize 90:7 recognized 107:20 recognizes 118:21 recommendation 75:3 recommendations 23:11,12,19 113:13 reconsideration 128:18 reconvene 110:17 record 6:3 28:7 50:15 75:20 88:3,12 110:21 119:3,16 124:4 125:12 126:2 143:7 145:20 146:16,18 159:13 174:7 recorded 34:6 60:20 records 111:19 112:11,12,14,15 114:19 115:9,11,12 116:12 117:11,14 123:5,15 124:17 126:4,19,22 127:3 129:20 140:3 141:2,6 142:20 143:8 145:21 recurring 104:19 redacted 135:13</p>	<p>145:21 redaction 128:19 redactions 128:7 redirecting 73:11 redouble 25:9 reduced 174:6 reducing 44:11 refer 128:17 172:2 referred 35:13 referring 170:17 regard 73:21 90:16 100:22 101:6,12 102:4,9,15 140:11,14 171:11 regarding 91:18 122:20 140:6 170:11 regardless 54:4 139:8 regards 100:21 region 57:17 regional 19:11 regions 19:11 register 23:1 28:1 59:15 68:14 79:2 91:13 97:16 110:18 163:9 164:15 registered 75:13 94:6 97:15 102:22 registry 78:13 82:11,17 97:14 104:14 regs 164:3</p>	<p>regular 97:9 105:9 regulated 74:8,20 161:7 162:8,17,22 regulation 17:21 46:5 47:21 92:13 103:22 113:2 117:20 140:1 regulations 23:16 29:10,22 45:21 46:3,17 47:1,11,13,21 49:9 79:2,12 87:11 92:20 102:3 114:6 140:19 141:5 163:1 168:9,12 regulations.gov 94:5 regulatory 1:7 2:3,7 3:11 17:16 18:16,22 19:8,16 20:2,12 23:7 31:19 45:1 72:1 75:1 79:13 83:16 85:19 95:22 117:22 159:17 173:9 Reinhold 6:22 38:1 reiterate 48:3 reiterating 94:18 relate 55:10 115:19 related 23:16 28:10 36:6 39:20 66:2,4 79:10 103:13 114:4 116:9 120:15 123:17 174:9</p>	<p>relating 117:15 relations 19:20,22 relative 174:11 relatively 54:7 138:4 release 17:22 22:14 25:13 113:4,18 119:6 120:4 123:20 126:2 147:15 released 114:4 124:17 127:1 releasing 119:20 127:3 relevant 45:15 51:15,16 101:9 108:14 reliable 94:9 118:13 remain 23:15 126:12,16 remains 24:15 remarks 6:7 15:2,7 16:19 27:3 30:14 61:5 remember 5:18 26:5 35:5 51:21 57:10 60:12 87:1 97:13 109:16 150:11 remind 75:12 172:10 reminded 49:9 removed 29:3 53:12 Rennet 8:7 repeated 127:21 report 55:19</p>
---	--	--	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 33

<p>64:8,12 66:18,20 67:3,10 72:10 87:18 114:5 149:6 150:12 155:3 156:8 157:11 164:9 reporter 5:9,10 125:14 133:12 174:1,19 reporting 149:3 150:3,17,22 151:7 153:2 156:8 157:8 reports 55:17 64:9 65:12 66:17 67:21 70:3 72:17 149:5,10,20 150:10 153:21,22 154:6,17 155:2 157:10,12,18 represent 170:5 request 111:20 114:18 115:3,21 116:2,19 117:5,7,10 118:17 119:3 122:9 123:1,3 125:9,10,18,19 128:11,13 129:9,13,14 131:15,16 133:18 135:14 136:10,19 137:1,2,3 138:7,13,16,21,2 2 139:2 142:2,5 143:1,2 145:19 147:3 requested 24:20 115:5 117:14 119:13 121:3</p>	<p>126:1 132:11 135:20 136:5 138:15 141:22 147:11 159:21 requester 128:20 131:4 134:11,13 145:22 requesters 129:17 131:5 requesting 129:4 requestor 116:12 123:5 124:8 requestors 117:14 requests 29:15 84:6 116:8,11 120:14 121:8 123:8 125:19 127:21 128:5 129:15 132:4 136:3 138:1,3,12 139:4,7,14 141:14 145:11,12,15 require 34:4,15,16,21 41:9 49:15 119:5 required 34:14 42:13 62:6 117:18,20 124:8 138:17 requirement 41:17 42:19 43:9,15 45:13 157:14 requirements 34:19 41:12 47:7 48:8 60:2,7 69:21 requires 53:3 114:12,13,14 re-review 128:22</p>	<p>research 9:14 162:8,16 researcher 17:2 resolution 24:12 resolved 169:18 resource 31:21 58:11,12 79:4 107:2 resources 20:9 21:11 24:11 26:20 35:15 38:5,7 43:14 51:10 65:18 71:17 72:12,20 73:6,7,12 79:11 97:12 107:3 169:7,8,20 respect 22:16 25:4,12 27:6 29:11 40:3 71:16 74:8 91:3 170:19 172:22 respond 15:13,16 59:13 60:9 67:16 86:1 127:11,13 167:17,18 responded 60:1 responding 50:21 56:18 response 39:17 59:11 73:3 112:9 121:7 123:1,4 125:9 126:11 138:13 144:5 145:20 responses 125:20 139:7 144:9 167:12 responsibilities 50:16 60:6 156:7</p>	<p>162:21 responsibility 105:18 responsible 26:14 43:2 114:6 responsibly 133:14 responsive 119:16 120:6 123:4 131:16 140:3 144:9 145:20,21 restated 96:7 restore 46:16 result 44:7 65:6 resulted 53:16 results 25:8 34:4,8 80:8 81:7 102:12 resume 75:18 159:11 retires 21:20 retiring 21:16 review 34:5,6 44:16 66:13 68:1 76:22 77:3 83:16 111:14 112:15 130:2,7,9 131:6 132:21 135:10 139:3 142:20 162:4 170:13 reviewed 45:20 124:12 reviewing 14:19 164:9 reviews 79:13 revise 168:12 revising 26:16 170:11</p>
---	---	---	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 34

<p>revisions 168:9,21 revive 168:8 Richard 9:2 42:1 47:1 rights 127:5 righty 88:9 risk 2:9 3:8 18:17 21:2 31:18 33:5 36:4,5 67:4 68:3 113:1 148:15 River 1:11 Riverdale 1:12 166:18 Riverside 1:10 Road 1:11 Rob 8:13 ROBERT 8:13 robust 39:14 62:11 90:14 96:3 Rogan 10:9 169:6 role 72:9 rolling 16:1 room 4:17 6:8 18:14 75:12 78:14 84:1,5 94:2 114:21 115:1,12,13,15 116:14,15,18 117:6,12 121:2 133:12 136:12,21 137:21 145:7,8 roped 106:10 Rosado 8:13 Roseland 2:11 12:22 33:16 38:20 39:1 46:12</p>	<p>rotation 54:11,14 Roundup 27:18 28:10 routinely 115:9 row 33:7 RSS 77:22 78:6 Ruckert 9:5 rule 36:3 rulemaking 34:13 rules 47:8 112:22 113:2 ruling 29:5,13 rulings 32:11 rumors 159:21 run 15:7 92:12 running 15:14 148:8 151:20 Russo 11:18</p> <hr/> <p style="text-align: center;">S</p> <hr/> <p>Sabrina 10:16 21:10 Sabrina's 21:12 sadly 159:16 safe 17:22 22:13 25:12 safety 59:1 114:1 Sally 11:2 satisfaction 23:14 satisfies 115:2 saved 73:12 saw 52:15 88:19 schedule 4:8 5:1 30:7,11 39:10 75:11 148:9</p>	<p>scheduled 75:9 schema 150:7 151:5 152:7,8,22 153:1 Science 9:8 sciences 72:15 scientific 58:6 scientifically 37:16 scope 45:17 scoping 43:21 63:13 Scotts 7:16 screen 41:22 162:20 scribe 87:22 88:1,2,3 scroll 85:4 scrunch 109:2 scrunchy 106:5 search 83:16 90:14 93:7 96:2,6 98:2,6 102:10,13,14 103:14 139:22 140:1,2,3 searching 103:14 season 94:1 seat 75:22 76:4 seats 88:14 110:22 second 80:13 121:11,18 128:11 144:19 156:21 Secondly 40:12 42:12 secret 113:7 118:7</p>	<p>Secretary 30:15,20 170:21 secrets 118:6 section 42:7 46:5 52:1 56:17 57:20 58:9,14,15 60:3 98:14 102:8 144:18 147:20 sections 104:21 sector 161:15 secure 150:14,15 security 112:20 seed 28:22 57:16 58:17 seeing 81:11 133:17 168:20 171:21 seek 45:20 seeking 29:2 seem 70:16 77:9 93:7 100:7 103:19 108:22 seemed 93:1 104:22 seems 35:7,22 52:12 70:19 104:22 seen 37:11 81:20 83:12 84:11 123:16 131:19 160:19 select 117:7 self-regulating 45:3 Senate 24:18 send 59:10 92:16 126:14 134:15 151:2,3,13</p>
---	--	--	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 35

152:11,15,20 sending 149:9 sends 126:11 senior 2:14 3:7 38:21 61:3 148:15 sense 87:9 89:6 126:1 169:14 sent 150:22 sentence 162:5 separate 18:19,22 20:1 59:14 95:16 123:7 152:21 separately 59:13 September 22:20 28:22 164:17 sequence 52:15 sequential 51:13 serve 93:3 167:1 service 1:6 60:8 64:22 68:9 services 1:7 2:3,7 9:14 18:16 56:11 85:19 96:4 159:1 173:10 session 2:4 3:1,13 15:16,19 21:19 76:5 110:12 111:1 166:12 sessions 169:13 sets 44:18 seven 31:17,22 several 35:8,11 74:3 129:15 shameless 82:10 share 14:11 63:22 64:1,5,16,20	130:11 142:10 155:7,16 166:21 shared 39:8 91:22 Sharie 8:9 93:18 122:20 sharing 72:10 Sharon 9:7 sheets 89:1 she'll 61:5 she's 134:10 144:2,3,4 shocking 46:11 shop 131:14 short 24:15 61:8 shortly 16:1 75:22 111:1 shoulders 89:2 shout-out 85:21 showed 36:19 122:21 144:20 showing 145:4 shown 36:18 121:10 shows 39:11 85:1 shy 172:21 Sid 12:14 166:11 167:21 168:1 sidebars 167:15 Sigma 26:22 170:19 sign 82:17 signed 4:11 42:1 104:14 significant 25:18 48:17 50:12,13 51:3 54:7	60:19,20 115:21 124:21 Sim 3:11 21:15 159:16,20 160:2 166:8 similar 92:7,9 100:21 101:5 143:21 Simmons 7:17,18 166:14,16 168:1,13 169:10 170:16 171:7,9,13 172:10 173:6 simple 52:12 single 138:2,6 Sinor 8:7 site 2:19 16:2,5 22:4,6 29:16 76:15 77:6,8,10,22 78:3,10,14,20 79:7,15,17 82:7,13,17,21 83:11,18 84:2,5,19,21 85:14,20 86:8 87:1,13 89:16,18,19 90:3 91:13,15 93:21 95:3,19 96:8 97:8,17 98:22 99:1,16 101:14,18 102:14 103:4,14 104:1,9,13,17 105:3,5 106:18,19 107:3,5,8,18 108:2 115:6 116:20,22 117:3 120:21	121:12,20 123:14 128:4 131:20 132:13 135:2 136:12 138:6 143:20 144:7,14,16,18,2 2 149:22 150:2,14,15 151:4,16,17 152:21 164:11 165:9,10 sites 90:8 93:22 95:21 sitting 86:14,18 situation 73:11 154:9 155:10 six 23:10 26:22 38:3 66:6 67:7 80:9 170:19 skipping 148:9 sleepy 166:4 slide 78:19 79:6 82:9 83:19 85:1 162:2 165:8 slideshow 38:14 slots 164:22 small 57:21 71:19 83:6 85:10 104:16 smaller 72:6 smarter 170:3 snapshot 116:15 121:9,10 144:20 145:4 147:6 so-called 133:1 social 59:4 socioeconomic 55:8,14 59:2,22
---	---	--	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 36

<p>soil 58:20</p> <p>sold 57:22</p> <p>solely 42:20</p> <p>solicited 59:7 163:8</p> <p>soliciting 164:16</p> <p>solutions 44:10</p> <p>somebody 102:10 105:8 109:16 143:16</p> <p>someone 21:6 74:13 75:13 97:13 101:6,10 105:6 115:5 160:22</p> <p>someone's 95:2</p> <p>sometime 71:6</p> <p>somewhat 27:4 96:6 156:9</p> <p>somewhere 90:18 171:15</p> <p>sooner 110:1 171:20</p> <p>soon-to-be 159:16</p> <p>sophisticated 93:8</p> <p>SOPs 170:11</p> <p>Sora 10:3</p> <p>sorry 98:20 99:21 104:5 122:9 132:15 133:10,13 135:18 137:1 144:17 147:3</p> <p>sort 4:21 5:5 20:16 31:3 61:18 69:11 70:16,20 71:5 77:21 79:2 81:20 86:14 87:11</p>	<p>91:22</p> <p>92:1,3,4,13</p> <p>94:16 100:22</p> <p>101:1,16 102:1</p> <p>104:18 105:1</p> <p>109:2 110:3</p> <p>123:7 131:13</p> <p>137:18 138:18</p> <p>139:8,9 140:15</p> <p>141:5 147:9</p> <p>156:5 160:3</p> <p>164:9 165:20 169:14</p> <p>sorts 81:21</p> <p>Sottosanto 11:19</p> <p>sought 24:7</p> <p>sounds 140:4</p> <p>sources 60:1 77:4,9 87:14 91:13 102:21</p> <p>Spaine 12:2</p> <p>span 19:14,15</p> <p>speak 33:6 61:12 76:19 130:14 134:8 144:1</p> <p>speaker 12:19 33:3 61:3 75:6 76:5 91:10 92:18 104:6 111:3 120:12 124:18 125:3,5 127:9 137:4,9,11 141:10,16 142:7,22 143:5,11 148:10,21 153:5,13 159:10,14,15</p> <p>speakers 33:7 35:3</p> <p>speaking 5:14,19</p>	<p>33:8 107:12</p> <p>special 44:1</p> <p>specialist 2:12,15 61:4</p> <p>specialists 38:2,21 59:10</p> <p>specialized 55:10</p> <p>specialty 57:16 58:18</p> <p>species 60:4</p> <p>specific 33:9 41:21 48:16 49:11,18 50:5 55:3 56:4 57:13 81:5 96:15 100:3 102:16 105:9 140:13 171:11,13</p> <p>specifically 121:1 140:12,16</p> <p>speckling 29:2</p> <p>specklings 32:8</p> <p>spectacularly 17:9</p> <p>speech 31:4</p> <p>speeches 30:15</p> <p>speed 80:20</p> <p>speedy 130:2</p> <p>spend 83:8 88:10 166:18</p> <p>spending 110:7</p> <p>spends 87:3</p> <p>spent 94:7</p> <p>spirit 14:9</p> <p>split 19:18</p> <p>spoke 105:16</p> <p>spraying 53:20</p>	<p>spread 38:4</p> <p>spreadsheet 85:5</p> <p>spring 68:17 70:16 71:7</p> <p>staff 2:3 4:5 10:11 18:13,19,20 19:1,10 20:4 21:12 22:3 24:2 26:19 36:1 37:20 73:7 84:7 94:16,21 95:13 105:17 115:18 130:1 164:18</p> <p>staffed 83:2</p> <p>staffing 101:22</p> <p>staff's 88:17</p> <p>stage 32:15 69:18</p> <p>stages 56:2</p> <p>stakeholder 1:8 13:17 59:19 78:12 82:11,16 91:18 94:6 97:14,15 104:14 116:5 144:1,7 172:18 173:10</p> <p>stakeholders 4:4 16:9 40:6,15 41:4,19 43:22 45:14 63:7,20 78:20 79:4 93:3 103:1 166:20 169:15</p> <p>Staley 8:16</p> <p>stand 105:10 110:9</p> <p>standalone 19:2</p> <p>standard 23:1 25:17 26:17 35:19</p>
---	--	--	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 37

<p>163:8,17,20 standards 35:16 Stander 6:14 standpoint 108:2,8 137:21 Stankiewicz 2:14 13:2,3 33:18 40:19 61:3,7,10 68:19 69:14 71:2 72:2 start 66:5 70:15 74:13 75:22 89:14 106:22 109:5,6,9,13 157:5 started 66:14,19 67:5,9 76:4 77:15 88:14,15 136:22 137:1 163:4 starting 9:3 35:14 37:6 102:5 132:3 starts 66:7 155:8 state 5:18 16:20 19:22 33:21 57:5 69:5 111:22 112:4 171:2 statement 27:8,10,13,20,21 28:16 34:17 35:1 42:19 46:7 50:11 51:4 162:3,18 static 96:12 status 29:11 34:21 39:21 50:21 75:1 89:21 91:4 93:11,12 94:12 103:7 168:10 statuses 104:10</p>	<p>statute 41:15,22 44:15,19 45:8 47:7 138:17 statutes 92:20 113:5 stay 4:8 82:9 staying 161:3 stenotype 174:5 step 59:5 68:13 96:1 STEPHEN 6:20 12:8 Stephon 7:6 97:3,6 99:3,5 steps 26:18 50:2 59:17 67:17 70:14,21 170:12 Steve 6:20 8:22 12:8 32:5 75:14 85:6 Stewardship 165:16 stink 89:10 stits 104:16 stop 161:1 story 37:1 106:2 strange 102:11 strategic 85:17,21 86:1 strategies 80:10 strength 81:11 107:15 strengthen 17:20 20:4 strengthening 17:15 22:12 25:5</p>	<p>strongly 170:21 structure 86:6 100:11,14 stuck 100:7,10 stuff 80:21 88:20 108:22 109:1,5 style 86:4,7 109:11 Su 10:21 subject 34:10 35:12 83:3 112:4,6 133:1 submissions 149:19 submit 67:2 70:4 94:22 129:9,13,16 149:4,11 150:11 155:1,3,4,22 158:3 submits 149:7 submitted 64:9 67:21,22 68:1 98:6,11,12 100:17 131:8 136:20 154:16 155:1 157:15 submitter 118:12,16,19 119:1,2,4,5,8,17, 18,20,22 120:2 124:1,2,7,20,22 126:11 127:10,11,13,15, 19 128:2 134:5,12,14 139:14 142:16 143:7,8 submitters 117:18 118:1,22 submitter's</p>	<p>119:10,12,14 120:3 submitting 67:7,10 98:9 130:3 154:17 subscribed 91:19 substantial 118:18,20 success 80:7 successful 44:8 sued 134:13 sufficient 50:2,9 sugar 27:15,16,18 28:10,20 29:17,19 32:7 suggested 39:16 108:1 suggestions 14:16 16:8 99:6 110:5 suit 28:21 summarize 51:2 summarized 42:3 summary 77:21 summation 50:22 88:5 summer 80:19 163:17 supervision 114:6 supervisor 19:13 supplement 20:8 supply 65:14 support 71:22 83:14 162:6 supposed 60:14 141:1 Supreme 29:13</p>
---	--	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 38

<p>47:10 Suraj 10:14 sure 4:8 5:14 13:22 24:13 63:15 77:10 79:15,16 80:20 83:8,11 131:9 135:8,11 156:3 158:1 159:8 160:7 165:11 167:8 170:1 surprised 13:20 172:16,20 Survey 79:8 switch 152:3 Syngenta 9:20,22 10:2 69:7 104:4 synthetic 37:9 system 3:9 16:16 22:18 25:16 62:20 80:15 81:1 82:2 94:14 95:15,16 96:22 149:14 156:20 systems 89:9,10 <hr/> <p style="text-align: center;">T</p> <hr/> table 5:22 14:21 16:12 76:14 86:13 88:6 89:4,7 93:19 94:6 100:1 102:22 104:4 109:15 132:5 136:6 tables 5:21 taking 35:17 40:3 42:7,10 52:3 62:9 66:7 165:4 166:17</p>	<p>talk 15:22 16:13 22:10 30:13 33:17,19 38:9 39:2,10 40:11 54:16 55:16 61:11,15 67:10 69:20 78:9,10,12 79:21 80:13 83:20 87:16 94:18 113:9 160:12 talked 20:15 58:16 77:7 80:4 109:21 143:13 169:4 talking 14:17 16:2 19:7 24:3 35:3 49:4 55:16 58:8 64:21 66:22 76:12 144:2,4 170:2 171:20 talks 33:12 38:17 42:17 tap 168:10 tapes 112:13 target 28:8 105:2 109:18 targeted 81:15 targets 81:7 tasks 156:19,20 Taylor 3:4 111:4,8,9 112:8,11 120:16,19 121:5,7,16 122:2,6 123:3,9,13 127:12,22 128:6,12 144:16,19 146:2,9,11,14,21</p>	<p>148:2 team 2:11 19:1,2,3,4 20:22 24:2 37:19 38:22 63:3 162:4 Tech 10:8 78:14 83:11,13 104:11 techniques 26:22 61:22 113:22 170:19 technologies 36:14 37:11 73:22 74:7,14 75:2 technology 114:19 teenage 77:15 teeny 84:3 templates 164:6 tend 61:10 term 18:5 terminology 81:4 98:19 terms 23:20 26:15 35:10,21 36:10,12,15 37:5,18 67:11 89:19 90:1,6,11,20 91:10,21 98:17 130:7,15 141:1,11 Terri 11:7 terrible 108:3 Tessa 12:6 test 62:16 149:6,21 150:10,14 151:17 157:11,13 testimony 174:5,8</p>	<p>testing 83:16 149:13,22 150:2 151:16 thank 13:7 32:1 33:13 61:1 68:18 75:19 76:1,16 88:2,11 91:7 93:16 97:1 102:18 104:2 105:13 106:12 108:19 110:7,11 126:9 143:11 147:20 148:1,2 153:3 155:18 159:6,12,19 166:9,16 173:6 Thanks 69:8 99:19 159:20 166:8 that'll 164:2 that's 5:19 6:4 16:17 25:1 26:13 30:11,19 31:4 33:12 43:12 44:14 45:13 52:4 57:16 60:14 67:14 68:17 73:16 76:9 77:18,20 78:11,16 79:5,16 80:1 81:11,13 82:7,18 83:9 84:4 85:17 86:1,6 87:2 88:20 91:4,22 98:1 99:19 100:12 104:6 107:10 108:1,17 109:18,20 110:15 117:8 121:9 126:2 128:10 129:8,18 130:14 132:5,12 133:1,5 136:6,16</p>
--	---	--	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 39

<p>139:4,5 140:21 141:4 147:8 149:8 151:21 153:13 154:11,21 156:1 157:1 158:15 165:13,21 168:1,3 170:1 171:9 173:5</p> <p>theme 14:1 92:1</p> <p>themes 22:11 94:15 104:19</p> <p>themselves 6:8 45:6 47:3,17 86:15 94:21 145:20</p> <p>theoretical 53:1</p> <p>thereafter 174:6</p> <p>therefore 154:5</p> <p>there'll 66:8 82:6 84:3</p> <p>there's 34:12 37:11,14 38:5 39:3 49:18 58:14 63:1 70:17 75:12 82:13 83:15,16,18 86:20 87:8,10,15 90:18 95:6 96:20 99:1 101:7,22 102:20 103:20 108:4 121:3,14 125:17 130:13,18 132:2 133:5 138:9,18 139:8,21 140:1,4 141:17 145:1 152:21 154:3 162:4,18 163:21 164:21 168:20,22</p>	<p>170:22</p> <p>they'll 129:1 164:14</p> <p>they're 36:12 37:21 48:1 52:7 64:21 74:15,19 96:14 100:8 103:3 133:18 134:5 140:21 147:6 160:5 162:20 169:12,15</p> <p>they've 86:5 135:12</p> <p>third 30:4 46:22 92:17 121:11</p> <p>Thirdly 40:14</p> <p>thorough 17:3 46:20</p> <p>thoughts 123:11 168:11</p> <p>threaten 60:4</p> <p>thrive 30:22</p> <p>throughout 63:21 66:8 70:8 110:19</p> <p>thrown 105:19</p> <p>tie 57:20</p> <p>tied 84:15</p> <p>timeframe 28:9 62:4</p> <p>timeframes 26:18 171:18</p> <p>timekeeper 4:7</p> <p>timeline 32:7</p> <p>timelines 171:11,13,20</p> <p>timeliness 38:12</p>	<p>62:18 65:5,13,19</p> <p>timely 38:8 99:7</p> <p>timewise 31:6</p> <p>tiny 84:4</p> <p>title 42:6 44:15,18 99:9</p> <p>today 4:6 13:19,22 14:1,10,18 16:18 18:14 21:19 30:4,12,17 39:10 40:9 61:16 77:4 85:22 111:11 160:5 169:12,16</p> <p>today's 14:19</p> <p>Todd 8:14,16</p> <p>tolerance 54:12</p> <p>tolerant 30:6</p> <p>Tom 3:11 21:15,16,18,19 159:16,18,19,20 166:2,6</p> <p>Tom's 22:1</p> <p>Tonya 122:6,8,14,16 133:22 134:8 135:15 143:12,22</p> <p>Tonya's 131:14 135:20</p> <p>tool 79:3 80:8 83:16 86:11 101:15</p> <p>tools 41:2 62:2,20 65:9 77:12 80:15 93:15 103:14 164:5</p> <p>top 80:11,17 81:1</p> <p>topic 83:7 168:16</p>	<p>169:2,19 170:5</p> <p>topics 33:8 79:1 115:20 137:17 141:3 168:14</p> <p>toss 89:2</p> <p>total 20:19 38:3</p> <p>touch 78:17</p> <p>tough 160:7</p> <p>toward 23:5 50:16 81:6 105:1 160:22</p> <p>TPQ 96:22</p> <p>tracking 82:3</p> <p>Tracy 2:17 9:9 21:4,5,6 76:7,12,15,17</p> <p>trade 59:3 113:7 118:6,7</p> <p>train 123:11</p> <p>training 37:22</p> <p>trait 49:17</p> <p>traits 107:7</p> <p>transcribe 6:1 89:3</p> <p>transcribed 5:12 109:5</p> <p>transcripts 78:1</p> <p>transferred 95:2</p> <p>transfers 99:17</p> <p>transition 147:20</p> <p>transparency 14:2,5 22:15 40:10 80:4 111:15 114:11,13,14 116:3,7 141:11,17</p>
--	---	--	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 40

<p>142:13 143:19 transparent 14:7 31:2 94:16 140:11 tremendous 36:16 trend 133:17 trial 160:21 trials 26:11 161:10 tribal 19:22 tried 82:1 161:5 trivial 112:22 trouble 38:14 true 129:8 174:7 truth 143:18 try 61:11,13 63:15 95:20 106:19 107:5 126:7 134:3 160:4 165:3,6 167:17 168:11 171:1 trying 26:10 60:17 71:14 101:10 109:20 143:18 157:10 165:19 tuned 82:9 tuning 81:18 turn 4:10 6:6 13:5 16:19 76:15 126:4 152:4 Turner 2:9 7:13 20:22 33:4,13 73:21 74:12 tweaking 152:14 Twitter 77:14,15,20 92:3 twofold 52:21 type 34:9,13 36:5</p>	<p>90:20 117:22 122:22 126:4 128:21 131:5 143:21 172:21 types 48:11 54:17 55:21 62:2 64:12 65:8 69:21 70:3 72:13 74:4 115:9 typewriting 174:6 typical 50:19 typically 36:18 58:15 128:17 131:17 134:1</p> <hr/> <p style="text-align: center;">U</p> <hr/> <p>U.S 1:5 30:22 32:11 41:3 43:14 79:8 95:21 111:21 uh-huh 32:2 127:22 128:15 136:3 141:15 Ultimately 46:8 unable 107:8,9 unbureaucratic 46:7 uncertainty 24:16 undergird 41:1 undergoing 66:13 underlying 46:4 understand 34:2 47:9 123:14 133:21 understandable 87:2 understanding 46:15 116:4 133:15</p>	<p>understatement 167:3 undertake 34:9 undertaken 51:8 undertakes 54:5 undertaking 64:19 underway 28:5 68:4 undoubtedly 106:21 uneventful 17:9 unidimensional 41:17 unified 78:10 79:7 95:21 unique 124:13 157:9 158:2,8 universe 102:16 unless 95:8 131:21 150:14 158:2 unwarranted 113:21 update 2:5 3:6,9 148:18 159:18 160:3 updated 90:18,21 91:5 99:7 100:8,9,17 103:15 144:14 updates 16:14 Upfront 153:4 upload 149:20 150:6,8,9 153:21 157:8,10,18 158:1,7 uploading 157:4 158:4</p>	<p>uploads 149:19,21 150:3 152:7 upon 94:1 100:3 121:4 URL 79:5,19 usability 85:19 usage 89:18 102:20 USDA 1:10 9:14 23:15 38:10 56:10 79:9 81:9 86:3 104:1 109:12 130:1,19 USDA's 85:17 86:4 useful 16:9 48:1 56:10 69:17 77:8,20 78:5,7 79:18 83:17 88:18 91:6 93:10 94:3,19 96:13 103:2 163:7 164:13,14 165:21 user 105:3 151:16,20 users 93:20 94:1 98:17 100:2 106:14,17 usually 35:6 117:21 118:2 127:12 129:1 132:20 134:15 utilize 64:15 96:20 114:19 165:1 utilized 93:22</p> <hr/> <p style="text-align: center;">V</p> <hr/> <p>valid 48:1</p>
--	--	---	--

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 41

<p>valuable 79:3 101:15 107:10</p> <p>value 40:9</p> <p>variable 89:18</p> <p>varied 91:11</p> <p>varieties 57:3</p> <p>variety 41:8,19</p> <p>various 44:16 107:4</p> <p>vendors 118:2</p> <p>version 100:10 128:22</p> <p>versus 102:14 130:16,22 131:1</p> <p>vet 159:1</p> <p>via 120:15</p> <p>viable 118:7</p> <p>view 41:7 116:19</p> <p>viewed 89:16</p> <p>views 30:1 134:16</p> <p>Vilsack 30:15,20</p> <p>Virginia 10:8 78:14 83:11,13 104:11</p> <p>vision 40:2</p> <p>visit 163:2</p> <p>visits 30:15</p> <p>volume 17:17</p> <p>voluntarily 118:1</p> <p>voluntary 62:6 72:3 118:3 162:6,11</p> <p>volunteer 149:5</p> <p>volunteered 161:20</p>	<p>votes 85:7</p> <hr/> <p style="text-align: center;">W</p> <hr/> <p>waiting 116:1</p> <p>walk 14:21</p> <p>Walker 10:18</p> <p>wander 61:11,12</p> <p>warmed 88:16</p> <p>was,You 78:2</p> <p>wasn't 13:22 90:14 91:19,20</p> <p>water 4:16 49:15 58:19</p> <p>waving 13:9</p> <p>ways 30:21 62:12,21 63:20 64:22 92:2 170:2</p> <p>wealth 106:1,8 108:10</p> <p>weather 13:19</p> <p>Web 2:19 5:12 16:2,5 22:4,6 29:16 76:14 77:6,8,10,22 78:3,10,14,19 79:7,17 82:7,12,17,21 83:11,18 84:1,19,21 85:14,19 86:5,8 87:1,13 89:16,18,19 90:3,8 91:13,15 93:5,20,22 95:3,19,21 96:8 97:8,17 99:16 100:9 103:4 104:9,13,17 105:3,4 114:20 115:5 116:20,22</p>	<p>117:3 120:20 121:12,20 123:14 128:7,17 129:2 131:20 132:13 135:2 138:5 139:4 141:7 143:20 144:7,14,16,18,2 2 145:3,13,17 151:4 152:21 164:10 165:9,10</p> <p>Weber 6:18 89:15</p> <p>we'd 22:6 39:22 69:15 86:19,22 90:20 130:5 161:2</p> <p>weeds 33:16</p> <p>week 9:3 22:20 79:14 86:2 89:17 91:12 152:16</p> <p>weekly 94:1</p> <p>weeks 5:13 81:14</p> <p>weigh 124:10,16 126:8,19 131:7</p> <p>weight 42:14 115:16</p> <p>weird 139:9</p> <p>welcome 2:2 4:3,19 13:17 110:16 166:19</p> <p>we'll 4:13 5:5,19,21 15:15 16:10,14,16 20:1 24:14 26:6,15 40:18 48:7 61:2 66:7 67:19 68:15 69:18,19,20 74:19,21 75:18,22 76:4 78:12,15 87:18</p>	<p>88:3 109:4,5,6 142:2 147:8 148:10 151:15 152:3,10 158:1,6 165:3 167:17 171:18</p> <p>we're 5:11 14:10,13,17 15:13 16:1,13 19:6 20:9 24:4 25:1,7,9,17 26:14,16,17,19,2 0 27:5,12 35:15 36:9 37:6,18 38:3,9 41:11 46:19 48:4,11 49:4 50:20 54:19 58:5,8 59:16 60:6 61:6,16 63:20 64:7,10,19,21 66:1,3,9,22 67:20 69:17 71:7 72:14 73:11,13 74:15,17 75:10 77:4,6 78:9,10 80:12 81:17 82:8 85:7 86:7,13,18 87:15 88:7,14 89:2 106:9 110:6 111:14 113:9 117:8,12 123:13 125:19 133:17 135:4,5,7 136:7,9 138:11,12,22 139:1,2,3,7 140:18 141:1 147:8 148:8,9,19 149:2,10,11,19 150:1,19 151:12 152:14 153:15 154:2,7,9 155:15 156:8 157:20</p>
--	--	---	---

Capital Reporting Company
 Biotechnology Regulatory Services Meeting 12-01-2010
 Page 42

<p>158:18 163:21 164:22 165:4,19 167:5 169:3,22 171:20 West 160:5 164:18 we've 13:4 18:7,18 19:3,9,14 20:18 23:21 24:1,2,3 36:9,18 37:10 52:11 55:7 56:9 58:2,4 59:5,6,16,17,19, 22 60:1 61:22 63:16 66:19 69:1,5 70:1 71:4 73:15 79:13 81:13 82:1,3 85:15 86:2,4,21 90:2,4 109:21 110:11 124:21 126:2,15 127:3 129:22 131:19 132:7 135:10 138:16,19,20 144:6,21,22 145:12 147:4 150:5,18 155:10,22 164:5,19 165:15 Whalen 8:5 whatever 117:10 131:1 137:7 Whereupon 173:9 whether 45:2 50:10 60:19 74:5,19 118:19 120:6 158:7 162:12 168:17,19 169:21 172:17 Whoa 97:4</p>	<p>whoever 84:17 88:3 156:13 whole 20:22 28:6 29:12 40:7 96:19 104:7,12 155:1,13 whom 18:13 174:3 whomever 147:6 Whoowho 88:20 who's 91:8 93:17 99:20 102:1 105:2,6 109:17 129:13,16,20 whose 109:19,20 wide 19:14 42:2,3 Wildlife 60:7 William 10:19 126:10 willing 142:10 wind 101:12 Wise 11:13 wish 50:20 162:12 wishes 22:1 withheld 119:21 120:8 128:20 134:7 withhold 112:19 113:3,6,17 114:3,8 119:12 120:6 132:1 134:3 147:10 witness 174:5,8 Witucki 9:19 wonder 71:17 wondered 69:9 wondering 74:4</p>	<p>Wood 12:11 Woods 122:8,16 124:2,19 125:11,17 126:13,18 127:17 128:16 129:6,8,12,15 130:17,20 132:7 134:10 135:4,21 136:1,3,8,22 137:3,6,14,19 138:9 139:12,18,21 140:17 141:15,19 142:15 143:4,6,15 144:6,13,17 146:13,16 147:1,13,15 148:1 work 16:21 17:1,18 19:1,9 24:4 25:2 27:21 28:4 39:9 56:6 67:5 72:16 73:13 79:20 80:1 81:2 90:4 99:7 109:13 113:14 118:21 154:22 157:17 158:21 165:3 170:3,4 172:13 worked 21:6 36:1,4 106:5 108:6,15 172:13 worker 59:1 working 23:21 39:6 65:2 66:14 69:16 80:15,19 81:13 101:2 105:18 108:12 109:5,9 142:19</p>	<p>153:15 154:2,8 155:8 164:18 165:15 171:16 workload 18:6,7 35:21 37:15 40:7 workloads 36:7 works 92:10 148:17 170:13 worth 135:6 wrap-up 16:17 write 126:20 140:18 writing 119:6 121:19 140:16 written 47:8 59:6 119:9 121:1 wrong 103:17 wrote 114:11 <hr/> X <hr/> XML 99:16 149:19,20 152:7 <hr/> Y <hr/> year's 135:6 yesterday 29:1,4 121:15 yet 4:12 24:22 27:14 61:19 80:18 153:14 yields 157:22 you'll 81:15 82:3 83:21 85:4 87:6 101:18 110:5 143:20 149:4 150:7,8,9 157:17 158:7 160:12 young 42:18</p>
--	--	---	---

<p>yourself 122:15 131:11 167:22</p> <p>yourselves 18:13 22:2 87:16</p> <p>Youst 42:4</p> <p>you've 71:18 101:4 105:6,8 108:21 126:15 154:14 158:2 167:13,15</p> <hr/> <p style="text-align: center;"><u>Z</u></p> <p>Zeph 10:2 69:7</p> <p>zero 97:10</p> <p>zinc 37:9</p>			
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