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UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 50-R-0001 CUSTOMER NUMBER: 41	FORM APPROVED OMB NO. 0579-0036
E I Dupont Denemours & Company Inc Haskell Laboratory Elkton Road P.O. Box 50 Newark, DE 19714		

NOV 18 2004

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	0				0
5. Cats	0				0
6. Guinea Pigs	0	39	0	0	39
7. Hamsters	152	0	0	0	0
8. Rabbits	0	399	0	26	425
9. Non-human Primates	0				0
10. Sheep	0				0
11. Pigs	0				0
12. Other Farm Animals	0				0
13. Other Animals	0				0

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)		
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	I NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11/2/04

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NOV 18 2004



DuPont Haskell Laboratory
for Health and Environmental Sciences
Elkton Road, P.O. Box 50
Newark, DE 19714-0050

November 22, 2004

Elizabeth Goldentyer, DVM
USDA, APHIS, AC
Eastern Regional Office
920 Main Campus Drive
Suite 200
Raleigh, NC 27606-5213

Dear Dr. Goldentyer:

To address the issue of the category E animals in the USDA annual report of the DuPont Haskell Laboratory for Health and Environmental Sciences (50-R-0001), I am providing a list of one type of skin irritation screen, two types of eye irritation studies and one pilot developmental toxicity study, which were conducted in rabbits to meet the criteria of various regulatory agencies or for safety assessment. All study protocols and SOP's were reviewed and approved by the Haskell Laboratory's Institutional Animal Care and Use Committee (IACUC).

Skin Irritation Studies

Four (4) rabbits that were used in the Skin Irritation Study experienced signs that were considered to fall into category E. These studies comply with or are based on (screening studies) test guidelines OPPTS 870.2500 (1998) and OECD 404 (1992).

Skin Irritation Study in Rabbits – The purpose of this study is to supply safety assessment information and to enable companies to file for pre-manufacturing notifications (PMNs).

Eye Irritation Studies

Nineteen (19) rabbits that were used in one of the following tests experienced signs that were considered to fall into category E. These studies comply with or are based on (screening studies) test guidelines OPPTS 870.2400 (1998) and OECD 405 (1987).

1. Eye Irritation Study - the purpose of this study is to supply safety assessment information and to enable companies to file for pre-manufacturing notifications (PMNs).
2. Eye Irritation Screen - the purpose of this study is to supply safety assessment information for Discovery compounds.

Testing for registration of crop protection chemicals is required under CFR 40 Part 158. Other testing is done for product stewardship purposes, for the reasons cited above.

The IACUC approved the conduct of these studies without the use of anesthetics, analgesics or tranquilizing drugs because the use of such drugs could adversely influence the experimental compound's effect on the animal or alter the animal's reaction to the experimental compound, resulting in invalid interpretation of the clinical signs by the scientists. Test guidelines (OPPTS) for these study types do not allow for the use of anesthetics, analgesics, or tranquilizing drugs, other than allowing use of local anesthetics in eye irritation studies where extreme pain is expected. Most tested substances are novel materials for which there is little or no information available upon which to predict the response. Test substances are not tested if it is expected they will produce corrosion or severe irritation (e.g., based on pH). The materials for registration studies are tested in step-wise fashion (one rabbit first, then two more if the first does not display severe response) if the test substance may be expected to produce a severe response, based on data from similar materials.

Pilot Developmental Toxicity Study

Three (3) rabbits that were used in the following test experienced signs that were considered to fall into category E. The pilot study set the dose level for the main study, which complies with test guidelines U.S. EPA Health Effects Guidelines OPPTS 870.3700. Prenatal Developmental Toxicity Study (August, 1998); International Conference on Harmonization (ICH). Tripartite Guidelines on Detection of Toxicity to Reproduction for Medicinal Products, Federal Register, September 22, 1994, Section 4.1.3.

1. Pilot Developmental Toxicity. The purpose of this study is to provide preliminary assessment of maternal and developmental toxicity of the test substance.

The IACUC approved the conduct of this study without the use of anesthetics, analgesics or tranquilizing drugs because the use of such drugs could adversely influence the experimental compound's effect on the animal or alter the animal's reaction to the experimental compound, resulting in invalid interpretation of the clinical signs by the scientists. Test guidelines (OPPTS) for this study type do not allow for the use of anesthetics, analgesics, or tranquilizing drugs.

General

DuPont actively supports research programs to develop scientifically acceptable refinements and alternatives to animal testing. We do use a commercially available in vitro system (Corrositex®) as a screen. We have also developed and validated the mouse local lymph node assay, which is used as a replacement for guinea pig dermal sensitization screening, where permitted by regulatory agencies. This assay is a refinement of the sensitization testing which involves much shorter exposures than the guinea pig assays. In those cases where the in vitro system provides sufficient

information, no additional studies with animals are performed. At present, there are no validated alternatives that would completely replace animal tests which are required by national and international laws and regulations.

Also, please note that there were no exemptions or exceptions to any USDA regulations and standards to report for this year.

Sincerely



UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 50-R-0004 CUSTOMER NO. 42

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

ASTRA ZENECA PHARMACEUTICALS
VETERINARY MEDICINE DEPT
P.O. BOX 15437 (1800 CONCORD PIKE)
WILMINGTON, DE 19850-5437

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

ZENECA BIOMEDICAL RESEARCH
WILMINGTON, DE 19850-5437

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs		34		37	71
5. Cats					
6. Guinea Pigs		1139	153	42	1334
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferret		28	29	40	97
Gerbil		45	771		816

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		10/06/2004

Signature

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 50-R-0004

2/3. Species (common name) & Number of animals used in this study:

Ferret (40)

4. Explain the procedure producing pain and/or distress.

Studies will be performed to determine whether potential candidate drugs have either emetic or anti-emetic properties. Anti-emetics have transformed the management of patients undergoing chemotherapy and radiation therapy for cancer. New drug candidates may prove more effective in man against delayed emesis induced either by cisplatin, post-operative nausea and vomiting, or motion sickness. Additional studies will be performed to complete a candidate drugs general pharmacology profile by determining whether the compound of interest has emetic potential. This latter experimental paradigm will be used most frequently. Compounds will be pre-selected for testing based upon pharmacological profile from various drug discovery efforts. There are no in vitro models of emesis, but there are several established animal models of emesis in dogs, cats, ferrets, rats, and gerbils. Ferrets respond to the same emetics and anti-emetics as humans and a large body of literature characterizing the species emetic responses and associated behaviors exists. Because of the homology with humans and extensive characterization of the ferret emesis model both within and outside of the company, fewer animals are needed to obtain statistically significant results and the ferret is the species of choice.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

Animals in this category are given an emetic agent which causes vomiting and retching. The objective of these studies is to determine experimental compounds' effects on the emetic response. In order to evaluate this effect, we cannot alleviate these distress responses (retching, vomiting) with drugs that would confound the measurements.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency:

CFR:

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 50-R-0004

2/3. Species (common name) & Number of animals used in this study:

Guinea Pigs (42)

4. Explain the procedure producing pain and/or distress.

Separation-induced vocalizations in guinea pig pups: Pups are placed individually in a testing box that is isolated from the home cage for a period not exceeding 15 minutes and the duration of vocalization is recorded. Experimental compounds effects on this response is evaluated after a control session.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

These studies are designed to assess compounds in animal models of human affective disorders; therefore, alleviation of distress would make these behavioral assays invalid.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency:

CFR:

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 50-R-0004

2/3. Species (common name) & Number of animals used in this study:

Dogs (37)

4. Explain the procedure producing pain and/or distress.

A preclinical safety/toxicology evaluation of a new pharmaceutical agent in dog is required by regulatory agencies worldwide.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

The data generated in these toxicology studies is required for New Drug Application submission to the FDA. This type of study in dog is useful because it requires a small number of animals and provides valuable information on acute toxic effects and drug-related adverse clinical signs. Determining the safety profile is only accomplished by administering compounds in increasing doses until adverse effects are observed. Alleviating those effects would make the studies invalid. Evaluations of the safety profile of a new pharmaceutical compound at this early stage of development, using small numbers of animals minimizes the need for larger scale studies in later stages of compound development.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency:

CFR:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT) <div style="text-align: right; font-size: 1.2em; font-weight: bold;">OCT 08 2004</div>	1. CERTIFICATE NUMBER: 50-R-0006 CUSTOMER NUMBER: 45	FORM APPROVED OMB NO. 0579-0036
University of Delaware Office Of Lab Animal Medicine x 220 Wolf Hall 020 Wolf Hall Newark, DE 19716 Telephone: (302) 831-2980 (302) 831-2400		

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquillizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquilz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reaso such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	15	6	25		31
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
White-Tailed Deer		119			119

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

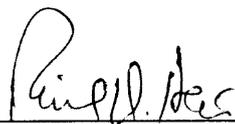
SIGNATURE	OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
			10/6/04

University of Delaware
Office of Lab Animal Medicine
020 Wolf Hall
Newark, DE 19716

Certificate Number: 50-R-0006
Customer Number: 45

FACILITY LOCATIONS (Sites)

- 020 Wolf Hall
- 046 McKinly Lab
- 133-138 Wolf Hall



Richard D. Holsten
Associate Provost for Research

10/6/04

Date

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 50-R-0009 CUSTOMER NUMBER: 47	FORM APPROVED OMB NO. 0579-0036
Nemours Foundation, The Alfred I. Dupont Hospital For Children 1600 Rockland Rd Wilmington, DE 19899 Telephone: (302) -651-6860		

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3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0		12		12
9. Non-human Primates					
10. Sheep					
11. Pigs	0		90		90
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
 (Chief Executive Officer or Legally Responsible Institutional Official)

NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED
11/14/04

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 50-R-0013 CUSTOMER NUMBER: 9014	FORM APPROVED OMB NO. 0579-0036
Strategic Diagnostics Inc. 128 Sandy Drive Newark, DE 19713 Telephone: (302)-456-6785		

NOV 29 2004

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing 52 Anderson Road
 Windham, Maine 04062

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs	36	117	0	0	117
7. Hamsters	0	9	0	0	9
8. Rabbits	4363	13,145	109	0	13,254
9. Non-human Primates					
10. Sheep	0	25	0	0	25
11. Pigs					
12. Other Farm Animals					
Goats	35	251	121	0	372
13. Other Animals					

ASSURANCE STATEMENTS

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)		
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED 04

APHIS Form 7023 (replaces US Form 10-23 (OCT 88), which is obsolete.) (AUG 91)