

303

1541.00

CONFIDENTIAL

OUTLINE OF PRODUCTION

ERYSIPELOTHRIX RHUSIOPATHIAE VACCINE,
AVIRULENT LIVE CULTURE

CODE 1541.00

from "Grand Labs" ✓

Novartis Animal Vaccines, Inc.
Larchwood, Iowa 51241
U.S. Vet. Lic. No. 303

January 30, 2002
Supersedes January 7, 2000 -

FILED with
USDA-APHIS-VS
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BIOLOGICS

MAR 26 2002

LICENSING & POLICY
DEVELOPMENT
NO ENDORSEMENT
EXPRESSED

ERYSIPELOTHRIX RHUSIOPATHIAE VACCINE,
AVIRULENT LIVE CULTURE

CODE 1541.00

Novartis Animal Vaccines, Inc.
U.S. Vet. Lic. No. 303

January 30, 2002

V. TESTING.

A. Purity.

9CFR 113.27(b). [redacted] (b)(4)
[redacted] (b)(4)

B. Safety.

9CFR 113.33(b)

9CFR 113.44 with the exception that [redacted] (b)(4)
[redacted] (b)(4)

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MAR 26 2002

LICENSING & POLICY
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ERYSIPELOTHRIX RHUSIOPATHIAE VACCINE,
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CODE 1541.00

Novartis Animal Vaccines, Inc.
U.S. Vet. Lic. No. 303

January 30, 2002

C. Potency.

Each serial and sub serial shall be tested for viable *E. rhusiopathiae* according to 9CFR 113.67(c)(2).

The minimum viable count [redacted] (b)(4)

The minimum viable count [redacted] (b)(4)

Serials with viable counts lower than the minimum on the initial test can be retested in accordance with 9CFR 113.8(b)(2).

The Following Information is Provided as per CVB Notice No. 98-02.

Claim	Dose	Route	[redacted]	Animal Age	Species	Reference	Date of Aphis Approval
Sows/Gilts	2 ml	IM	[redacted] (b)(4)	breeding	porcine	Report 10, 05/13/87	7/31/87
Piglets	1 ml	IN		newborn	porcine	Report 10, 05/13/87	07/31/87
	1 ml	IN		newborn	porcine	Report 11, 11/06/87	03/08/88*
Feeder Pigs	2 ml	IN		25-35 lb.	porcine	Report 4, 11/07/86	01/13/87
	2 ml	IM		25-35 lb.	porcine	Report 9, 05/13/87	07/31/87
Repeat Immunogenicity	2 ml	IM		40 lb.	porcine	Report 16, 09/09/98	08/11/99

[redacted] (b)(4)

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Novartis Animal Vaccines, Inc.
U.S. Vet. Lic. No. 303

January 30, 2002

D. Moisture, if Lyophilized.

Refer to Section IV. H.

E. Identity Test.

Approximately (b)(4)

(b)(4)

(b)(4) The media will be incubated a maximum of 48 hours at 35°-39°C. The test is valid if the morphological and biochemical reactions of the positive control are typical of *Erysipelothrix rhusiopathiae*:

Test

Expected result for

(b)(4)

~~VI. POST PREPARATORY STEPS.~~

~~A. Form and Size of Final Containers in Which the Product is to be Distributed.~~

Container Form

Container Size

(b)(4)

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ERYSIPELOTHRIX RHUSIOPATHIAE VACCINE,
AVIRULENT LIVE CULTURE

CODE 1541.00

Novartis Animal Vaccines, Inc.
U.S. Vet. Lic. No. 303

January 30, 2002

DECLARATION OF CONFIDENTIAL INFORMATION

The firm submits detailed Outline of Production, only in order to present evidence of the product's origin or organisms used, methods of attenuation, production and evaluation of its safety, and its capacity to elicit desirable protection in recommended species. This information is considered confidential by the firm and should be protected from disclosure to any party making requests under the Freedom of Information Act (FOIA). Disclosure of information from this submission, even in part or minor fragmentary information, would provide persons who have even modest knowledge and skill in biological production, adequate insight of the firm's methods and concepts, and would result in irreparable economic harm to the firm.

The request for confidentiality is crucial to the firm's continuing desire to present complete and objective reports of its experimental and developmental studies on new products. Further, the firm has expended large sums of money in the conceptualization, development, and refinement of production and evaluation methods of the product.

More specifically, the firm considers confidential the following information in the Outline of Production:

Part I Sections	Composition of the Product (b)(4)
Part II Sections	Cultures (b)(4)
Part III Sections	Harvesting (b)(4)
Part IV Sections	Preparation of Product (b)(4)
Part V Sections	Testing (b)(4)

Questions or comments regarding this matter and relating to this subject product may be addressed to:

✓ From Grand Labs → APHIS Liaison
 Novartis Animal Vaccines, Inc.
 1447 140th Street
 Larchwood, IA 51241
 Telephone (712) 477-2811

(b)(6)

#6 (b)(6)

(b)(6) 03-23-02

3-25-02

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MAR 26 2002

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DEVELOPMENT
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303
2110.00

CONFIDENTIAL BUSINESS INFORMATION - PROPERTY OF NOVARTIS ANIMAL HEALTH US, INC.

OUTLINE OF PRODUCTION

ACTINOBACILLUS PLEUROPNEUMONIAE-BORDETELLA BRONCHISEPTICA-
ERYSIPELOTHRIX RHUSIOPATHIAE-HAEMOPHILUS PARASUIS-
PASTEURELLA MULTOCIDA BACTERIN

CODE 2110.00

090528 aor *chg*

Novartis Animal Health US, Inc.
Larchwood, IA 51241
U.S. Vet. Lic. No. 303

2015 has
12/14/09
May 28, 2009
Supersedes May 28, 2008
Complete Revision *added*

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BIOLOGICS

NOV 19 2009

POLICY, EVALUATION, AND LICENSING
NO ENDORSEMENT
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81927
OCT 15 2009 11/19/09

ACTINOBACILLUS PLEUROPNEUMONIAE-BORDETELLA BRONCHISEPTICA-
ERYSIPELOTHRIX RHUSIOPATHIAE-HAEMOPHILUS PARASUIS-
PASTEURRELLA MULTOCIDA BACTERIN ✓

CODE 2110.00 ✓

090528 aor ✓

U.S. Vet. Lic. No. 303

May 28, 2009
Complete Revision 

I. Amount of Antigenic Material per Dose or Doses in Final Container.

(b)(4)

1. *Actinobacillus pleuropneumoniae*
2. *Bordetella bronchiseptica*
3. *Erysipelothrix rhusiopathiae*
4. *Haemophilus parasuis*
5. *Pasteurella multocida*

(b)(4)

(b)(4)

The antigen levels are determined at harvest prior to inactivation.

V. TESTING.

A. Purity.

9CFR 113.26.

(b)(4)

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ACTINOBACILLUS PLEUROPNEUMONIAE-BORDETELLA BRONCHISEPTICA-
ERYSIPELOTHRIX RHUSIOPATHIAE-HAEMOPHILUS PARASUIS-
PASTEURELLA MULTOCIDA BACTERIN ✓

CODE 2110.00 ✓

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May 28, 2009
Complete Revision ✱

B. Safety.

1. 9CFR 113.33(b). Details are described in Special Outline 8-104. (b)(4)

(b)(4)

2. 9CFR 113.38. Details are described in Special Outline 8-103. (b)(4)

(b)(4)

C. Potency.

1. *Actinobacillus pleuropneumoniae* (APP) Serotypes (b)(4)

Completed product shall be tested for potency using ACTINOBACILLUS
PLEUROPNEUMONIAE SEROTYPE (b)(4) POTENCY (b)(4) TEST (Special
Outline 8-031).

a.

b.

(b)(4)

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ACTINOBACILLUS PLEUROPNEUMONIAE-BORDETELLA BRONCHISEPTICA-
ERYSIPELOTHRIX RHUSIOPATHIAE-HAEMOPHILUS PARASUIS-
PASTEURELLA MULTOCIDA BACTERIN ✓

CODE 2110.00 ✓

090528 aor ✓

U.S. Vet. Lic. No. 303

May 28, 2009
Complete Revision

c. Criteria for a Satisfactory Serial.

1)

2)

3)

(b)(4)

Stage	# of Vaccinates	Cumulative # of Vaccinates	Cumulative # of Live Vaccinates For	
			Satisfactory Serial	Unsatisfactory Serial
1				
2			(b)(4)	

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ACTINOBACILLUS PLEUROPNEUMONIAE-BORDETELLA BRONCHISEPTICA-
ERYSIPELOTHRIX RHUSIOPATHIAE-HAEMOPHILUS PARASUIS-
PASTEURELLA MULTOCIDA BACTERIN ✓

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May 28, 2009
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2. *Bordetella bronchiseptica.*

Completed product shall be tested for potency using BORDETELLA
BRONCHISEPTICA POTENCY (b)(4) (Special Outline 8-030).

a. Criteria for a Valid Test.

1)

2)

(b)(4)

b. Criteria for a Satisfactory Serial.

(b)(4)

1)

2)

(b)(4)

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ACTINOBACILLUS PLEUROPNEUMONIAE-BORDETELLA BRONCHISEPTICA-
ERYSIPELOTHRIX RHUSIOPATHIAE-HAEMOPHILUS PARASUIS-
PASTEURELLA MULTOCIDA BACTERIN

CODE 2110.00

090528 aor ✓

U.S. Vet. Lic. No. 303

May 28, 2009
Complete Revision



3)

[Redacted block containing (b)(4)]

Stage	# of Vaccinates	Cumulative # of Vaccinates	Cumulative # of Live Vaccinates For	
			Satisfactory Serial	Unsatisfactory Serial
1			(b)(4)	
2			(b)(4)	

3. *Erysipelothrix rhusiopathiae*.

Completed product shall be tested for potency using the ERYSIPELOTHRIX RHUSIOPATHIAE ELISA POTENCY TEST (Special Outline 8-080).

a. *E. rhusiopathiae* Reference.

"05/17/2009"

[Redacted block containing (b)(4)]

December 31, 2009

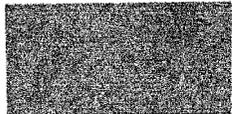
The Reference is adjusted to [Redacted block containing (b)(4)]

[Redacted block containing (b)(4)]

b. Dilution of the Test Serial, Reference and Negative Control.

The Test Serial, Reference and Negative Control [Redacted block containing (b)(4)]

[Redacted block containing (b)(4)]



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POLICY, EVALUATION, AND LICENSING
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ACTINOBACILLUS PLEUROPNEUMONIAE-BORDETELLA BRONCHISEPTICA-
ERYSIPELOTHRIX RHUSIOPATHIAE-HAEMOPHILUS PARASUIS-
PASTEURELLA MULTOCIDA BACTERIN

CODE 2110.00

090528 aor ✓

U.S. Vet. Lic. No. 303

May 28, 2009
Complete Revision



c. Relative Potency Calculation Method.

The method used to calculate the relative potency value of the test serial is the Relative Potency software program version 3.1 or the current version available from the Center for Veterinary Biologics-Policy, Evaluation and Licensing Laboratory, 1800 Dayton Road, P.O. Box 844, Ames, Iowa 50010.

d. Criteria for a Valid Assay.

A valid assay is one which results in valid, parallel lines in an unequivocal test as determined by the Relative Potency software program.

Any test session that does not fulfill the criterion of a valid assay may be repeated without prejudice.

e. Criteria for a Satisfactory Serial.

1)

2)

a)

b)

(b)(4)

(b)(4)

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ACTINOBACILLUS PLEUROPNEUMONIAE-BORDETELLA BRONCHISEPTICA-
ERYSIPELOTHRIX RHUSIOPATHIAE-HAEMOPHILUS PARASUIS-
PASTEURELLA MULTOCIDA BACTERIN ✓

CODE 2110.00 ✓

090528 aor ✓

U.S. Vet. Lic. No. 303

May 28, 2009
Complete Revision (8)

4. *Haemophilus parasuis*.

Completed product shall be tested for potency using the HAEMOPHILUS
PARASUIS (b)(4) Special Outline 8-037).

(b)(4)

a. Criteria for a Valid Assay.

(b)(4)

b. Criteria for a Satisfactory Potency Test.

(b)(4)

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POLICY, EVALUATION, AND LICENSING
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ACTINOBACILLUS PLEUROPNEUMONIAE-BORDETELLA BRONCHISEPTICA-
ERYSIPELOTHRIX RHUSIOPATHIAE-HAEMOPHILUS PARASUIS-
PASTEURELLA MULTOCIDA BACTERIN ✓

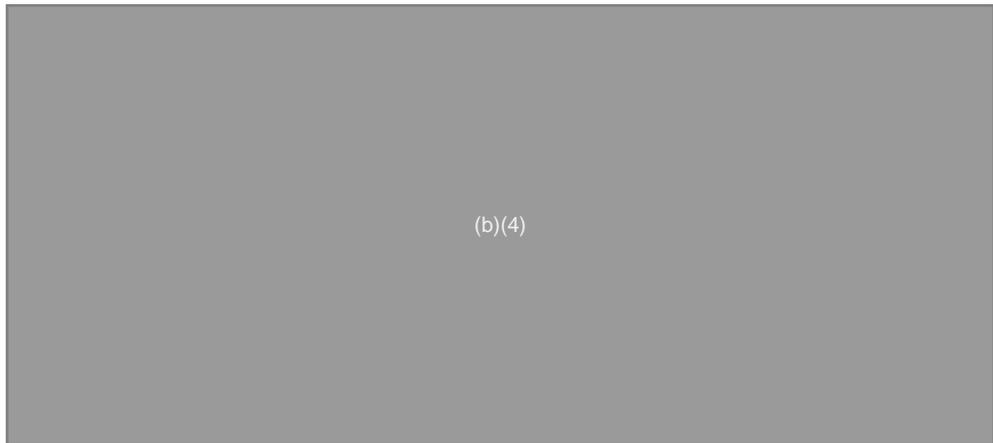
CODE 2110.00 ✓

090528 aor ✓

U.S. Vet. Lic. No. 303

May 28, 2009 
Complete Revision

c. Criteria for a Satisfactory Second Stage Potency Test.



5. *Pasteurella multocida*.

9CFR 113.121(c).

D. Moisture if Desiccated.

Not Applicable.

E. Any Other Tests.

9 CFR 113.100(f)(2).

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ACTINOBACILLUS PLEUROPNEUMONIAE-BORDETELLA BRONCHISEPTICA-
ERYSIPELOTHRIX RHUSIOPATHIAE-HAEMOPHILUS PARASUIS-
PASTEURELLA MULTOCIDA BACTERIN

CODE 2110.00

090528 aor

U.S. Vet. Lic. No. 303

May 28, 2009
Complete Revision

DECLARATION OF CONFIDENTIAL INFORMATION

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Specifically, the firm stipulates the (b)(4) exemption is applicable to the confidential business information in this document, as listed below:

Part I Sections	Composition of the Product (b)(4)
Part II Sections	Cultures (b)(4)
Part III Sections	Harvest (b)(4)
Part IV Sections	Preparation of Product (b)(4)
Part V Sections	Testing (b)(4)

(b)(6)

(b)(6) QA

(b)(6)

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NOV 19 2009

POLICY, EVALUATION, AND LICENSING
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(b)(6) 10/09

revised

Est. 303
2641.00

CONFIDENTIAL BUSINESS INFORMATION - PROPERTY OF NOVARTIS ANIMAL HEALTH US, INC.

OUTLINE OF PRODUCTION

ERYSIPELOTHRIX RHUSIOPATHIAE BACTERIN

CODE 2641.00

100224 aor *chg* ✓

Novartis Animal Health US, Inc.
Larchwood, Iowa 51241
U.S. Vet. Lic. No. 303

February 24, 2010 ^{2015 has} ← 5/6/10
Supersedes February 25, ~~2000~~ 2009
Complete Revision

Submitted May 6, 2010

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BIOLOGICS

JUL 13 2010

POLICY, EVALUATION, AND LICENSING
NO ENDORSEMENT
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ERYSIPELOTHRIX RHUSIOPATHIAE BACTERIN

CODE 2641.00
100224 aor

U.S. Vet. Lic. No. 303

February 24, 2010
Complete Revision

V. TESTING.

A. Purity.

9CFR 113.26. Volume of medium

(b)(4)

Added

The Preservative Interference Study was approved in CVB correspondence dated Aug. 3, 1999.

B. Safety.

9CFR 113.38. Details of testing can be found in Special Outline 8-103,

(b)(4)

(b)(4)

C. Potency.

i.

(b)(4)

a.

from

(b)(4)

b.

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ERYSIPELOTHRIX RHUSIOPATHIAE BACTERIN

CODE 2641.00

100224 aor

U.S. Vet. Lic. No. 303

February 24, 2010

Complete Revision

c. Relative Potency Calculation Method.

The method used to calculate the relative potency value of the test serial is the Relative Potency software program version 3.1 or the current version available from the Center for Veterinary Biologics-Policy, Evaluation and Licensing Laboratory, 1920 Dayton Ave., Ames, Iowa 50010.

1/3 comma Corrected street address /

d. Criteria for a Valid Assay.

A valid assay is one which results in valid, parallel lines in an unequivocal test as determined by the Relative Potency software program.

Any test session that does not fulfill the criterion of a valid assay may be repeated without prejudice.

e. Criteria for a Satisfactory Serial.

1.

(b)(4)

2.

a.

(b)(4)

b.

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POLICY, EVALUATION, AND LICENSING
NO ENDORSEMENT
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ERYSIPELOTHRIX RHUSIOPATHIAE BACTERIN

CODE 2641.00

100224 aor

U.S. Vet. Lic. No. 303

February 24, 2010
Complete Revision

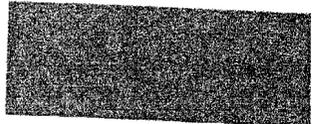
D. Moisture, if Desiccated.

Not applicable.

E. Any Other Tests.

9CFR 113.100 (f)(2)

Ref. SAM



~~VI. POST PREPARATORY STEPS.~~

~~A. Form and Size of Final Containers in Which the Product is to be Distributed.~~

Container Form

Container Size

(b)(4)

(b)(4)

Completed product may be exported in unlabeled final containers. Approved labels will be applied to the boxes used to ship the unlabeled final containers.

~~B. Collection, Storage, and Submission of Representative Samples.~~

Samples will be handled as specified in 9CFR 113.3 and VS Memorandum 800.59 (sampling of biological products) and 9CFR 114.11 (storage of biological products). Representative samples may be collected in regular containers that are partially filled.

Serial samples in final containers may be exported for concurrent testing prior to APHIS release.

Recipient Facility

Sample Quantity

QC Manager
Novartis Animal Health K.K.
World Trade Center Bldg. 37F
2-4-1, Hamamatsu-cho
Minato-ku
Tokyo 105-6137

(b)(4)

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POLICY, EVALUATION, AND LICENSING
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ERYSIPELOTHRIX RHUSIOPATHIAE BACTERIN

CODE 2641.00

100224 aor

U.S. Vet. Lic. No. 303

February 24, 2010

Complete Revision

DECLARATION OF CONFIDENTIAL INFORMATION

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Specifically, the firm stipulates the (b)(4) exemption is applicable to the confidential business information in this document, as listed below:

Part I Sections	Composition of the Product (b)(4)
Part II Sections	Cultures (b)(4)
Part III Sections	Harvest (b)(4)
Part IV Sections	Preparation of Product (b)(4)
Part V Sections	Testing (b)(4)

This production outline has been prepared and reviewed by Technical Operations personnel and is being submitted under my signature as the authorized representative of Novartis Animal Health US, Inc. U.S. Vet Lic. No. 303.

(b)(6)

(b)(6)

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Revised

Revised

6-17-10

7/9/10

303

S.O. 8-030

CONFIDENTIAL BUSINESS INFORMATION - PROPERTY OF NOVARTIS ANIMAL HEALTH US, INC.

BORDETELLA BRONCHISEPTICA POTENCY (b)(4)

SPECIAL OUTLINE

8-030

090528 aor *chg*

Novartis Animal Health US, Inc stipulates that the (b)(4) exemption applies to the confidential business information contained in this document; thereby exempting disclosure under the Freedom of Information Act. *added*

Novartis Animal Health US, Inc.
Larchwood, Iowa 51241
U.S. Vet. Lic. No. 303

2015 has
May 28, 2009 *10/6/09*
Supersedes May 28, 2008 - *8/26/08*
Complete Revision

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BIOLOGICS

DEC 18 2009

81872
OCT 13 2009 *NY 12/1/09*

POLICY, EVALUATION, AND LICENSING
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BORDETELLA BRONCHISEPTICA POTENCY (MOUSE)

SPECIAL OUTLINE

8-030
090528 aor *chg*

U.S. Vet. Lic. No. 303

May 28, 2009 ** 2015 has 10/6/09*
Complete Revision *← added*

The following reagent will be provided to CVB-L upon test request: challenge culture.

I. MATERIALS.

A.

(b)(4)

B. Reagents and Supplies.

1. Peptone Buffer.

Item

Amount*

(b)(4)

(b)(4)

2.

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BORDETELLA BRONCHISEPTICA POTENCY (MOUSE)

SPECIAL OUTLINE

8-030
090528 aor *chg*

U.S. Vet. Lic. No. 303

May 28, 2009 &
Complete Revision

3.

(b)(4)

II. METHODS.

A. Animal Procedures.

(b)(4)

B. Challenge Preparation.

1.

2.

3.

4.

(b)(4)

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BORDETELLA BRONCHISEPTICA POTENCY (MOUSE)

SPECIAL OUTLINE

8-030
090528 aor *ckg* ✓

U.S. Vet. Lic. No. 303

May 28, 2009 *
Complete Revision ✓

C.

(b)(4)

1. Standardize the challenge material as described in Section II.B.

2.

3.

4.

(b)(4)

III. TEST CRITERIA.

Refer to the Production Outline.

deleted IV. Other Information as per.
This special outline has been prepared and reviewed by Technical Operations personnel and is being submitted under my signature as the authorized representative of Novartis Animal Health US, Inc. U.S. Vet Lic. No. 303.

(b)(6)

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NO ENDORSEMENT
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(b)(6)

11/23/09

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S.O.# 8-031

CONFIDENTIAL BUSINESS INFORMATION - PROPERTY OF NOVARTIS ANIMAL HEALTH US, INC. ✓

ACTINOBACILLUS PLEUROPNEUMONIAE SEROTYPES 1, 5 & 7 POTENCY

(b)(4)

SPECIAL OUTLINE ✓

8-031 ✓

080528 aor - added ✓

"Complete Revision"

Novartis Animal Health US, Inc. ✓
Larchwood, Iowa 51241 ✓
U.S. Vet. Lic. No. 303 ✓

May 28, 2008 ✓
Supersedes July 3, 2007 ✓

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POLICY, EVALUATION, AND LICENSING
NO ENDORSEMENT
EXPRESSED

ACTINOBACILLUS PLEUROPNEUMONIAE SEROTYPES 1, 5 & 7 POTENCY

(b)(4)

SPECIAL OUTLINE ✓

8-031 ✓
080528 aor - added ✓

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JB "Complete Revision"

The following reagents will be provided to CVB upon test request: NBAP's

(b)(4)

I. MATERIALS.

A.

B.

(b)(4)

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ACTINOBACILLUS PLEUROPNEUMONIAE SEROTYPES 1, 5 & 7 POTENCY (MOUSE) ✓

SPECIAL OUTLINE ✓

8-031 ✓
080528 aor - added ✓

U.S. Vet. Lic. No. 303 ✓

May 28, 2008 ✓
Complete Revision

S/B

I. B. 2.

(b)(4)
(b)(4)

Ingredient

Amount*

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

3.

ACTINOBACILLUS PLEUROPNEUMONIAE

(b)(4)

(b)(4)

(b)(4)

4.

(b)(4)

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NO ENDORSEMENT
EXPRESSED

ACTINOBACILLUS PLEUROPNEUMONIAE SEROTYPES 1, 5 & 7 POTENCY

(b)(4)

SPECIAL OUTLINE ✓

8-031 ✓
080528 aor - added ✓

U.S. Vet. Lic. No. 303 ✓

May 28, 2008

"Complete Revision"

II. METHODS.

A. Animal Procedures.

(b)(4)

B. Challenge Preparation.

1.

2.

3.

(b)(4)

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POLICY, EVALUATION, AND LICENSING
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ACTINOBACILLUS PLEUROPNEUMONIAE SEROTYPES 1, 5 & 7 POTENCY

(b)(4) ✓

SPECIAL OUTLINE ✓

8-031 ✓
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U.S. Vet. Lic. No. 303

May 28, 2008

"Revision"

II. B. 4.

(b)(4)

For Example:

	ml of	
<u>Dilution</u>	<u>Standardized Suspension</u>	<u>ml of HGM</u>

(b)(4)

(b)(4)

C.

(b)(4)

- 1.
- 2.
- 3.
- 4.

(b)(4)

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ACTINOBACILLUS PLEUROPNEUMONIAE SEROTYPES 1, 5 & 7 POTENCY

(b)(4)

SPECIAL OUTLINE

8-031 ✓
080528 aor - added

U.S. Vet. Lic. No. 303 ✓

May 28, 2008 ✓
"Complete Revision"

II.

D.

(b)(4)

E.

III. TEST CRITERIA.

Refer to the Production Outline.

IV. OTHER INFORMATION.

Novartis Animal Health US, Inc. considers the information in this Special Outline confidential and exempt from disclosure under the Freedom of Information Act.

This special outline has been prepared and reviewed by Technical Operations personnel and is being submitted under my signature as the authorized representative of Novartis Animal Health US, Inc. U.S. Vet Lic. No. 303.

(b)(6)

#L (b)(6)

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(b)(6) 5-08

303
S.O. 8-037

CONFIDENTIAL BUSINESS INFORMATION - PROPERTY OF NOVARTIS ANIMAL HEALTH US, INC. ✓

HAEMOPHILUS PARASUIS PIG POTENCY TEST ✓

SPECIAL OUTLINE ✓

8-037 ✓
081217 cc - *added*

Novartis Animal Health US, Inc.
Larchwood, IA 51241 ✓
U.S. Vet. Lic. No. 303

December 17, 2008
Supersedes July 11, 2006

2015 Jan
"1-15-09"

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MAY 12 2009

POLICY, EVALUATION, AND LICENSING
NO ENDORSEMENT
EXPRESSED

HAEMOPHILUS PARASUIS PIG POTENCY TEST ✓

SPECIAL OUTLINE ✓

8-037 ✓
081217 cc - added ⊗

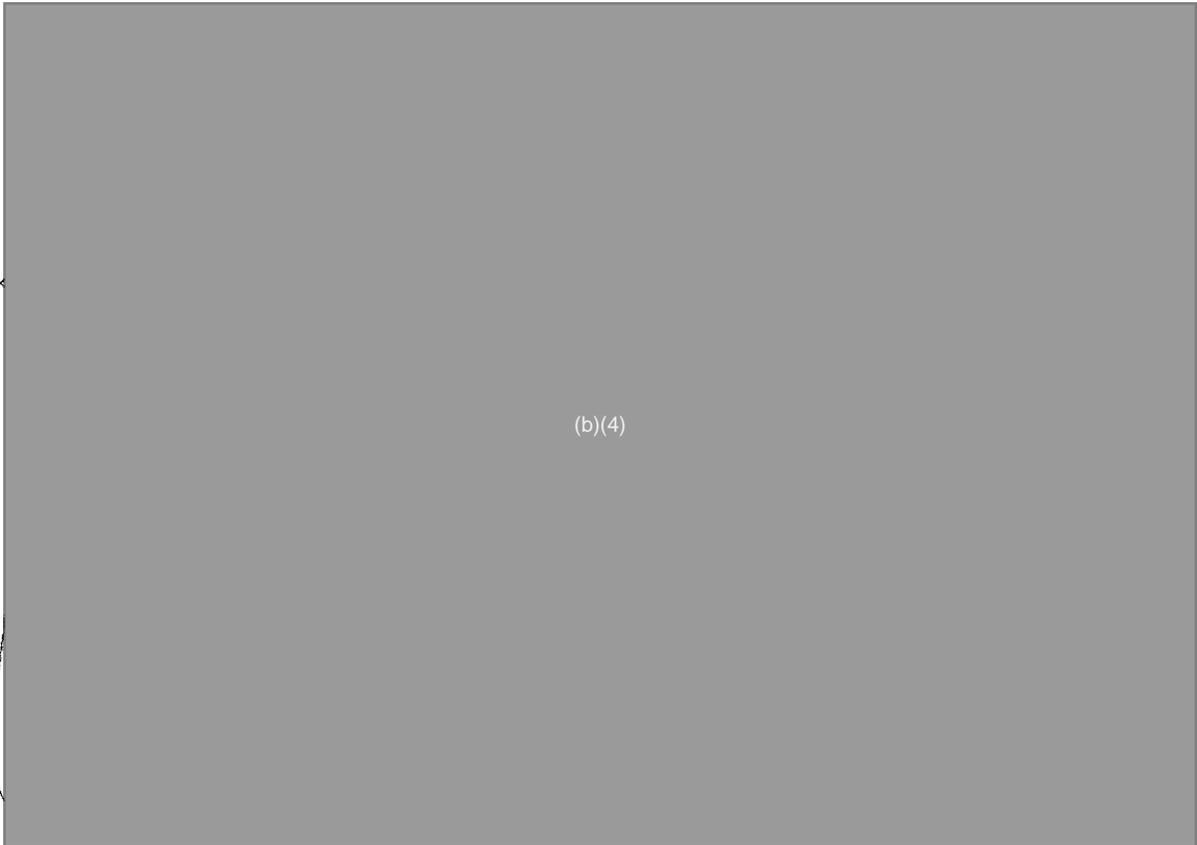
U.S. Vet. Lic. No. 303 ✓

December 17, 2008
Complete Revision

* 2015 has
1/15/09

I. MATERIALS AND METHODS.

A.



✓ Revised

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MAY 12 2009

POLICY, EVALUATION, AND LICENSING
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EXPRESSED

HAEMOPHILUS PARASUIS PIG POTENCY TEST ✓

SPECIAL OUTLINE ✓

8-037 ✓
081217 cc (X)

U.S. Vet. Lic. No. 303

December 17, 2008 *
Complete Revision

S/B

I. B. [Redacted] (b)(4)

[Redacted] (b)(4)

[Redacted] (b)(4)

C. [Redacted] (b)(4)

[Redacted] (b)(4)

[Redacted] (b)(4)

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HAEMOPHILUS PARASUIS PIG POTENCY TEST ✓

SPECIAL OUTLINE ✓

8-037 ✓

081217 cc (X)

U.S. Vet. Lic. No. 303

December 17, 2008 ✗
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II. DATA ANALYSIS.

A. Criteria for a Valid Assay.

For the test to be valid, ^{revised ✓} the following conditions must be met:

(b)(4)

B. Data Analysis.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Example	Test Group			
1	(b)(4)	(b)(4)	(b)(4)	(b)(4)
2				
3				

(b)(4)

C. Criteria for Satisfactory Serial.

✓ added

As per the threshold of acceptance defined in Section II.B. and referenced in Section V.C. of the Outline of Production.

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SPECIAL OUTLINE ✓

8-037 ✓
081217 cc 

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December 17, 2008 *
Complete Revision

III. APPENDICIES

A. Procedure for Random Number Assignment

1. MATERIALS.

a. Pen, paper and container

2. PROCEDURES.

a. Procedure for random numbers assignment using the
"Blind Assignment" method.

(b)(4)

added

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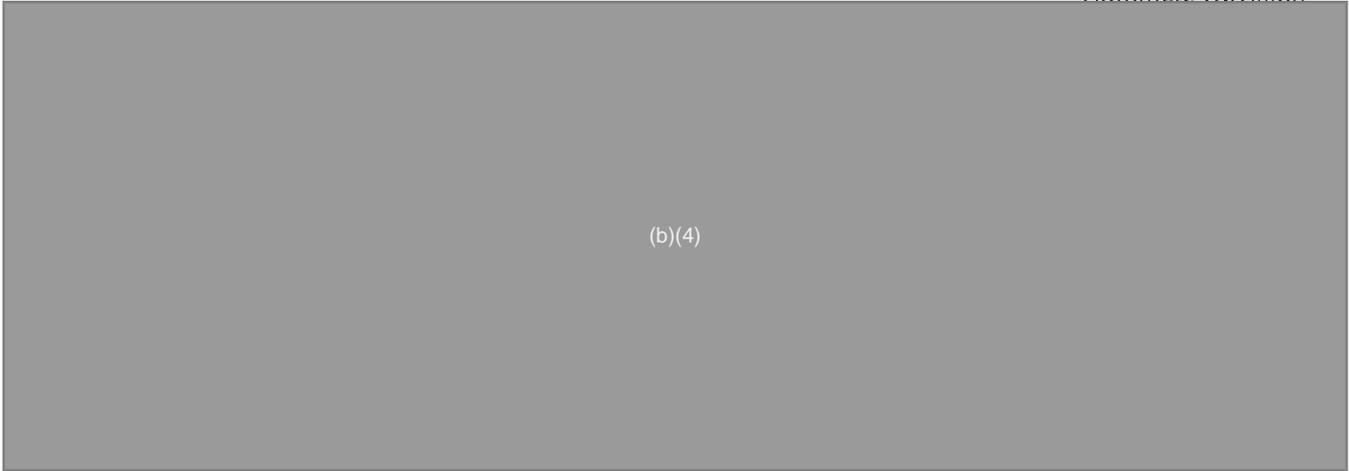
HAEMOPHILUS PARASUIS PIG POTENCY TEST ✓

SPECIAL OUTLINE ✓

8-037 ✓
081217 cc (X)

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December 17, 2008 ★
Complete Revision



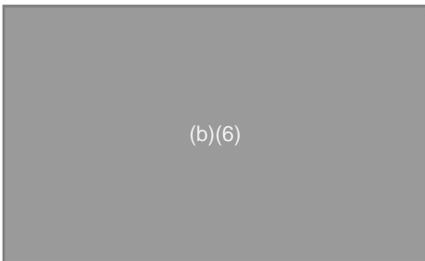
(b)(4)

res
" III "

IV. OTHER INFORMATION.

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2/5/09

Cat 303
S.O. 8-080

CONFIDENTIAL BUSINESS INFORMATION - PROPERTY OF NOVARTIS ANIMAL HEALTH US, INC.

ERYSIPELOTHRIX RHUSIOPATHIAE ELISA POTENCY TEST

SPECIAL OUTLINE

8-080

100224 aor *chg*

Novartis Animal Health US, Inc. Stipulates that the (b)(4) exemption applies to the confidential business information contained in this document; thereby exempting disclosure under the Freedom of Information Act. *} added*

Novartis Animal Health US, Inc.
Larchwood, Iowa 51241
U.S. Vet. Lic. No. 303

February 24, 2010 *2015 res*
Supersedes March 25, 2008 *5/6/10*
FILED WITH
Complete Revision *Submission*
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JUL 02 2010

POLICY, EVALUATION, AND LICENSING
NO ENDORSEMENT
EXPRESSED

ERYSIPELOTHRIX RHUSIOPATHIAE ELISA POTENCY TEST

SPECIAL OUTLINE

8-080

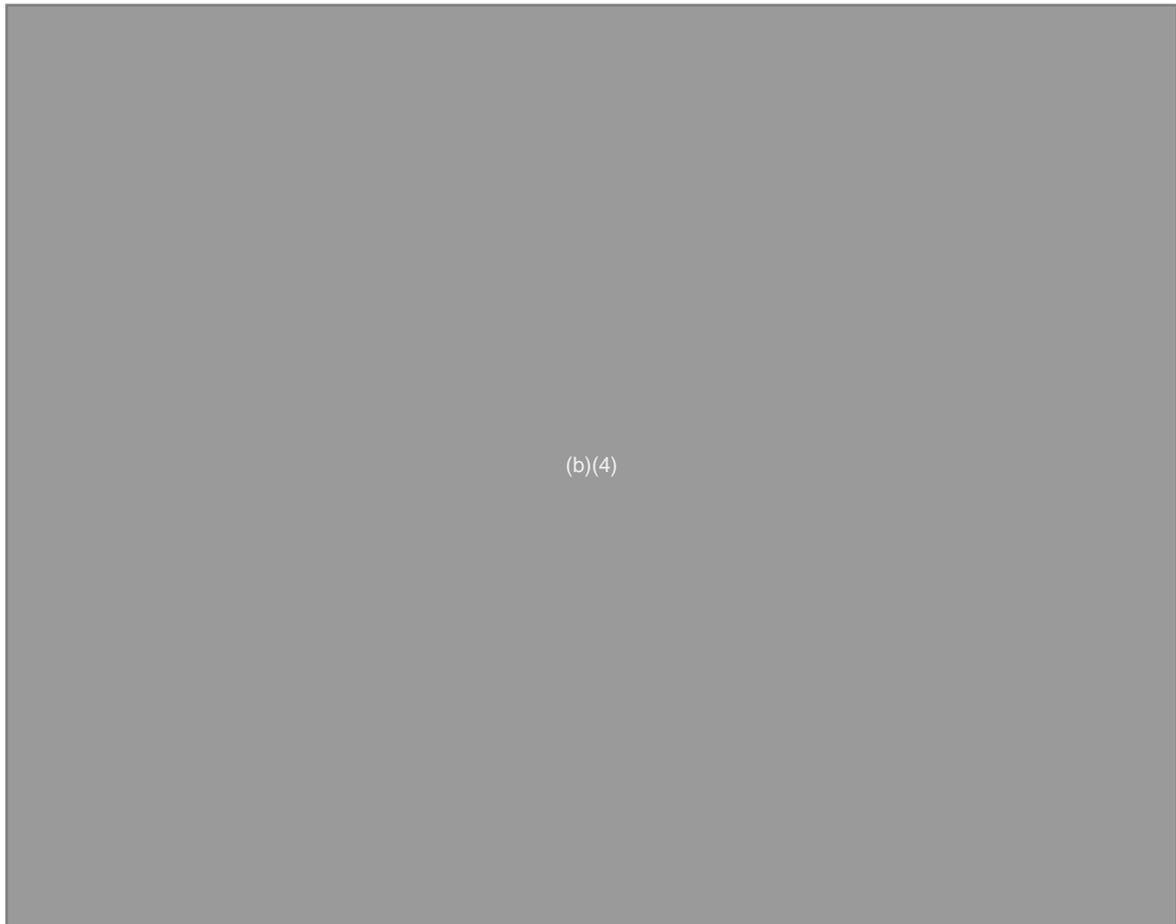
100224 aor *Chg all headers*

U.S. Vet. Lic. No. 303

February 24, 2010
Complete Revision

*2015 hrs
5/6/10*

I. MATERIALS.



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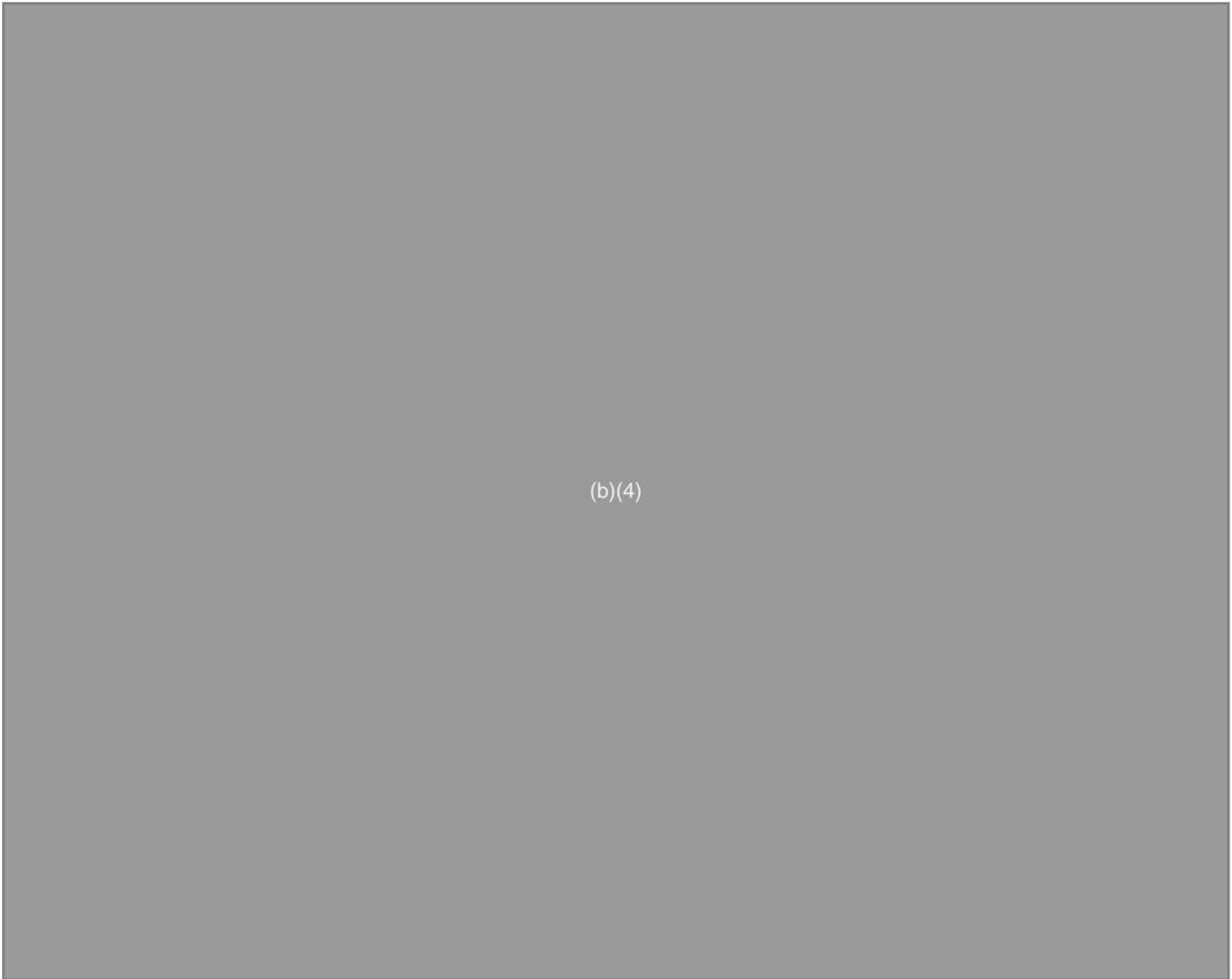
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SPECIAL OUTLINE

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(b)(4)

J. Negative Control.

Serial BP1138. This serial was made according to the production outline for Code 7150.00 (BORDETELLA BRONCHISEPTICA-CLOSTRIDIUM PERFRINGENS TYPE C-ERYSIPELOTHRIX RHUSIOPATHIAE- ESCHERICHIA COLI-PASTEURELLA MULTOCIDA BACTERIN-TOXOID) except without the *E. rhusiopathiae* fraction.

K. ELISA Plate.

ELISA grade 96-well flat bottom microtitration plates (Immulon-2; Dynatech Laboratories, Inc. or equivalent).

L. Dilution Plate.

96-well "U" bottom microtitration plates.

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ERYSIPELOTHRIX RHUSIOPATHIAE ELISA POTENCY TEST

SPECIAL OUTLINE

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II. METHODS.

~~A.~~

(b)(4)

~~B.~~

(b)(4)

C.

D. Plate Coating.

(b)(4)

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E.

F.

G.

(b)(4)

H.

I.

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J.

K.

L.

M.

N.

(b)(4)

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SPECIAL OUTLINE

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U.S. Vet. Lic. No. 303

February 24, 2010
Complete Revision

O. (b)(4) for Optimizing Assay Parameters.

1. (b)(4) is used to evaluate new lots of (b)(4).
(b)(4) The procedure used for the (b)(4)
(b)(4) is listed below.

a.

(b)(4)

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ERYSIPELOTHRIX RHUSIOPATHIAE ELISA POTENCY TEST

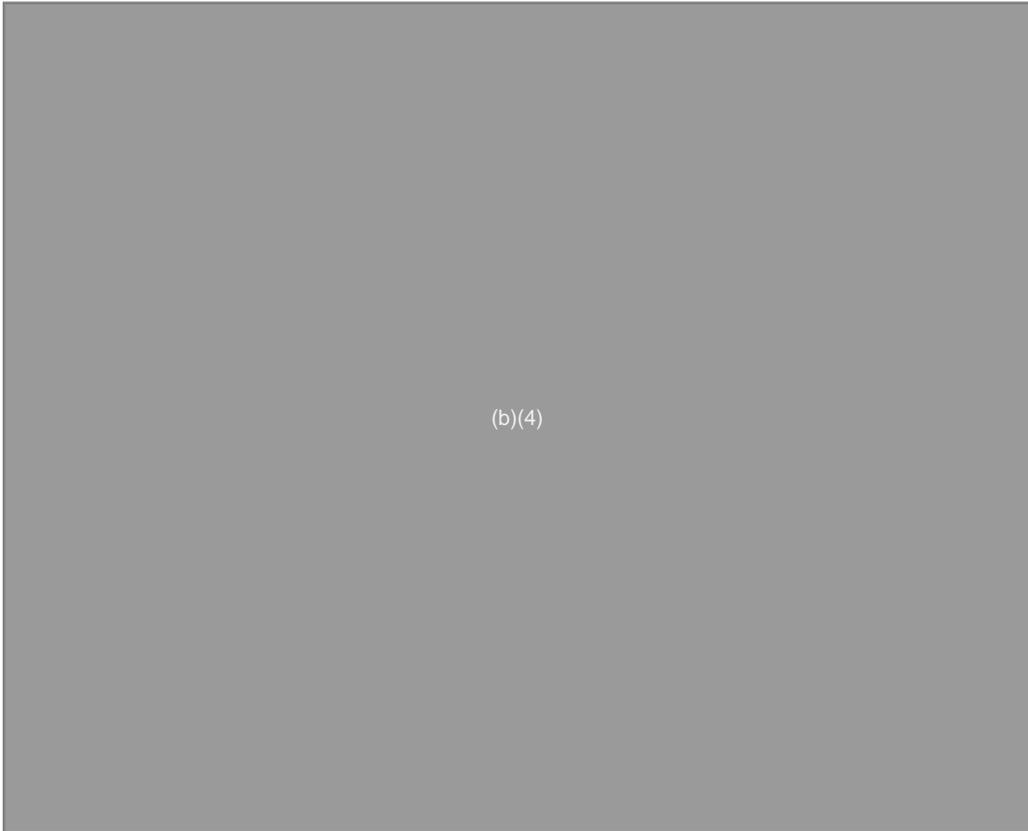
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SPECIAL OUTLINE

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2. The highest sensitivity of the assay is determined by evaluating the following parameters (b)(4)

a.

b.

c.

d.

(b)(4)

An example of the (b)(4) described and the individual steps are listed below.

e.

f.

g.

(b)(4)

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SPECIAL OUTLINE

8-080

100224 aor

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February 24, 2010
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III. DATA ANALYSIS.

A. Relative Potency Calculation Method.

Refer to Specific Outline of Production.

B. Criteria for a Valid Assay.

Refer to Specific Outline of Production.

C. Criteria for a Satisfactory Serial.

Refer to Specific Outline of Production.

✓
deleted "IV. Other Information" - revised statement moved to cover pg.

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(b)(6)

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(b)(6)
b 11-10

(b)(6)
11/30/10

303
S.O. 8-103

CONFIDENTIAL BUSINESS INFORMATION – PROPERTY OF NOVARTIS ANIMAL HEALTH US, INC. ✓

GUINEA PIG SAFETY TESTING ✓

SPECIAL OUTLINE ✓

8-103 ✓

080528 aor - added ✓

"Complete Revision"

Novartis Animal Health US, Inc. ✓
Larchwood, IA 51241 ✓
U.S. Vet. Lic. No. 303 ✓

May 28, 2008 ✓
Supersedes January 3, 2007 ✓

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GUINEA PIG SAFETY TESTING ✓

SPECIAL OUTLINE ✓

8-103 ✓
080528 aor - added

U.S. Vet. Lic. No. 303 ✓

May 28, 2008 ✓
"Complete Revision"

I. MATERIALS.

A. (b)(4)

1. (b)(4)

II. METHODS.

A. Each of (b)(4)
(b)(4)

B. Observe (b)(4) Observations will be recorded as:

- 1.
 - 2.
 - 3.
 - 4.
 - 5.
 - 6.
 - 7.
- (b)(4)

deleted out page format

*added per p+i
not in Summary*

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GUINEA PIG SAFETY TESTING ✓

SPECIAL OUTLINE ✓

8-103 ✓
080528 aor - added

U.S. Vet. Lic. No. 303 ✓

May 28, 2008 ✓
"Complete Revision"

III. INTERPRETATION OF RESULTS.

A. (b)(4) Satisfactory.

B. (b)(4) Unsatisfactory or Inconclusive test (b)(4)

C. (b)(4) per p. 2

(b)(4)

(b)(4) Unsatisfactory or Inconclusive. (b)(4)

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GUINEA PIG SAFETY TESTING ✓

SPECIAL OUTLINE ✓

8-103 ✓
080528 aor - added

U.S. Vet. Lic. No. 303 ✓

May 28, 2008
"Complete Revision"

*linked font
get chg format
padding*

*9/8
III. (D)
it in
summary ✓
was "E."*

If [redacted] (b)(4) the product
will be declared **Unsatisfactory**. If the [redacted] (b)(4)
test is declared **Inconclusive** and a [redacted] (b)(4)
[redacted] (b)(4) **Unsatisfactory**.

IV. OTHER INFORMATION. — *chg to all caps*

Novartis Animal Health U.S., Inc. considers the information in this Special Outline confidential and exempt from disclosure under the Freedom of Information Act.

*added
spaces*

This special outline has been prepared and reviewed by Technical Operations personnel and is being submitted under my signature as the authorized representative of Novartis Animal Health U.S., Inc., U.S. Vet. License No. 303.

[redacted] (b)(6)

#1 [redacted] (b)(6)

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[redacted] (b)(6)
15.08

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S.O.# 8-104

CONFIDENTIAL BUSINESS INFORMATION - PROPERTY OF NOVARTIS ANIMAL HEALTH US, INC.

MOUSE SAFETY TESTING

SPECIAL OUTLINE

8-104

Novartis Animal Health US, Inc.
Larchwood, IA 51241
U.S. Vet. Lic. No. 303

January 3, 2007
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FEB 06 2007

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MOUSE SAFETY TESTING

SPECIAL OUTLINE

8-104

U.S. Vet. Lic. No. 303

January 3, 2007

I. MATERIALS.

(b)(4)

II. METHODS.

(b)(4)

III. INTERPRETATION OF RESULTS.

A. If no reactions (b)(4) the test meets requirements and is **Satisfactory**.

B. All tests which (b)(4) will be assigned an **Unsatisfactory or Inconclusive** test disposition pending diagnostic evaluation. (b)(4)

(b)(4) This report will be filed with QA and in the serial file upon completion of the test.

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FEB 06 2007

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MOUSE SAFETY TESTING

SPECIAL OUTLINE

8-104

U.S. Vet. Lic. No. 303

January 3, 2007

(b)(4)

The test disposition will be assigned, either **Unsatisfactory** or **Inconclusive**, (b)(4)

C. (b)(4) (b)(4) **Unsatisfactory.** (b)(4) (b)(4) **Inconclusive** (b)(4) (b)(4)

IV. Other Information.

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08-01-07

(b)(6)

#6
(b)(6)