

**United States Department of Agriculture
Center for Veterinary Biologics**

Standard Operating Policy/Procedure

**Review of Center for Veterinary Biologics Office Files
for Pre-Inspection Packets**

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Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

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Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

1. Purpose and Scope

This document outlines the procedures for gathering and reviewing the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) office files before an on-site inspection. The items incorporated are collectively known as a “Pre-Inspection Packet” (PI Packet). Several worksheets are maintained in CVB databases for each licensed establishment to be incorporated into the PI Packet.

2. Regulations

2.1 Disclosure of confidential business information contained in an Outline of Production or any other document containing trade secrets to an unauthorized person is a violation of the Trade Secrets Act, 18 U.S.C. 1905, and may be grounds for fine, imprisonment, or dismissal.

2.2 Office files contain a wide variety of material used to prepare for an inspection. However, official files shall not be removed from the office. In some cases, photocopies of documents may be taken for purposes of inspection, but should be protected from unauthorized disclosure.

3. Procedures

3.1 The Biologics Compliance Assistant (BCA) will supply a PI Packet to the Biologics Specialist (Specialist). Refer to **Appendix X**, *Checklist for BCAs*, for items the BCAs are responsible for providing.

3.2 A copy of the packet is initiated by the BCA **2 weeks** prior to the in-depth inspection, based upon the IC Schedule. The BCA will confirm with the Specialist that the inspection will occur before the work is done.

3.3 Each team member of the inspection team, as indicated on the IC Schedule, receives a copy of the PI Packet.

3.4 As part of the preparation for the inspection, the Specialist should check the accuracy of the information during the review of the CVB-IC office files.

3.5 There are a number of reports that are maintained electronically for each licensed or permitted establishment. The following numbered items are references as to the location of the specified reports needed to complete a packet. In certain instances, some information may only need to be cross-checked.

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4. Items from the [REDACTED]
Database

4.1 Establishment [REDACTED]

BCA: Obtain a printout from [REDACTED] of the [REDACTED].

Specialist: The following information shown on the [REDACTED] report may also be cross checked against the Establishment License (see **Appendix I**):

- Firm: This is the Official Name of the Licensee.
- Mailing Address: This is not necessarily the same as the Official Address or the address(es) of the licensed premises.
- Official Address: Note that the mail address and firm locations may be different from the official address.
- Establishment License Number: The license number will also appear on all [REDACTED] reports, test reports, etc.
- Subsidiaries and Divisions: These are important when labels and trade names are checked. If a division is listed on a label, the subsidiary or parent company must be mentioned also. Refer to the Code of Federal Regulations, Title 9 (9 CFR), Part 112.4.
- Locations of Licensed Premises: These are important when plot plans are checked. Referred to as Sites, also lists the addresses of each site within the Establishment Profile. If one or more site locations are in close proximity to another licensed location of the same establishment, these may be grouped together with only the primary address listed.
- Date of Issue: Using the establishment license, note the Current Licensed Date. Compare with older, obsolete licenses and note recent changes. The first license date and current license date are noted in the Establishment Profile report, along with Reissue Reason.
- ** For Foreign Permittees, the following are differences from the Domestic Establishment License: product allowed to be imported, the location of foreign manufacture, the location for importation, and special conditions or restrictions (See **Appendix IV**).

4.2 Product Licenses [REDACTED]

BCA: Obtain a printout of [REDACTED] from [REDACTED]

Specialist: The following information should be compared with the Product License or Permit License with the printout for each product that is licensed (see **Appendices III and IV**):

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4.3 Product License

BCA:

Obtain a printout of [redacted] from [redacted]

Specialist:

The information in the [redacted] report should be checked similarly as in **Section 4.2**.

- These items should be checked and compared against the Pending Files located with CVB-Policy, Evaluation, and Licensing (CVB-PEL).
- Be sure to note if the new organism is listed in the filed facility documents. Note any special requirements in connection with the prelicensing application procedures. Also, note any product distribution that CVB-PEL has authorized under 9 CFR 103.3.

4.4 [redacted] Personnel

BCA:

Obtain a printout from [redacted] of [redacted] [redacted] (see **Appendix V**).

Specialist:

This information should be compared against the APHIS Form 2007 on file with CVB (see **Appendix VI**). The following may be verified:

- The Official Liaison and the Alternates for the firm, including Site Contacts are current.
- The Government Samplers have been authorized by personnel in CVB-IC. A list of Authorized Samplers can be printed from [redacted]
- Persons responsible for Serial Release Contact are up-to-date.
- Review the Organizational Chart, copy if needed.
- Principal Officers. Look at the application for the establishment license (APHIS Form 2001), if on file. Note the principal officers of the organization on the worksheet. This information may be

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needed when key decisions are made concerning inspection findings. Obtain a copy from CVB-PEL, if needed.

4.5 Labels and Trade Names

BCA: Obtain a printout of currently approved labels from [REDACTED]. Each licensee is required to submit a list of all approved labels currently being used when requested (9 CFR 112.5 [f]).

Obtain a printout of [REDACTED]

Specialist: Review the printout against the labels on file at CVB; may only include those that are planned for audit while on inspection.

- Note temporary and/or expired labels, if any. Document comments during the pre-inspection meetings concerning labels that need special attention while on inspection.
- The Outline of Production may be checked to see if each dosage size is allowed with each product.
- Review the label file and list of trade names that are not listed on current labels.
- For products that have been selected to audit, record trade names on the product check-off sheet for convenience later at the firm.

4.6 Master Seeds and Master Cells

BCA: Obtain a printout of [REDACTED] used by the firm from [REDACTED].
Obtain a printout of [REDACTED] used by the firm from [REDACTED].

Specialist: Note items that may be of interest to investigate while on inspection.

- Review the files at CVB for accuracy of the report. These may be helpful for trace back of master seeds/cells at the firm. Information included in the Master Seed report may be Agent Name, Lot ID, Date Approved, Species or Type/Strain. Information in the Master Cell report may include Cell Name, Lot ID, Baseline Passage tested, or Maximum Passage.

4.7 FDA – Export Reform and Enhancement Act

BCA: Obtain a printout of the [REDACTED] on file in [REDACTED]

Specialist: Double check the report against the files in the CVB-PEL pending drawer.

Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

5. Items from [REDACTED]

5.1 [REDACTED] Report

BCA: Obtain a printout of the firm's testing records using [REDACTED]
[REDACTED]
Consult with the Specialist to determine the dates to use. This will be sent via interoffice mail.

Specialist: Analyze the licensee's summary.

- Analyze those serials that have been unsatisfactory. Past test results indicate product that may need special attention.
- Check the Outline of Production and 9 CFR Standard Requirements in Part 113 to verify the requirements for satisfactory product.
- Prepare a tentative list of products that seem to need attention while at the firm. Select product codes that have not been previously reviewed. Try to select representative sampling of the firm's products to review: one serial near expiration, one serial halfway through dating, and one that has been recently produced or is still in process. For each selected product, note serial number, trade name, important points, etc. on the Product Check off Sheet for later use at the firm.
- Check the report for serials the CVB-PEL found unsatisfactory "UNS". The destruction of these serials may need to be observed during the inspection and documented on the APHIS Form 2045. See **Section 7.5** for further instructions.

5.2 [REDACTED] Serials

BCA: Obtain a copy of the printout of [REDACTED]
[REDACTED]

Specialist: Go through the list of [REDACTED] serials. This may contain information that may further identify items that may need special attention at the firm.

5.3 Special Test [REDACTED]

BCA: Obtain a copy of the printout of [REDACTED]
[REDACTED]

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5.4 Test Codes [REDACTED]

BCA: Obtain a copy of all the [REDACTED] used at the present time for a particular firm.

5.5 List of Products [REDACTED]

BCA: Obtain a printout of licensed products for a firm [REDACTED]. This includes the product, the status, effective date, and the date last produced.

Specialist: This report is useful to determine the products not produced in the last 5 years. See 9 CFR 105.4.

6. Items from the Administrative Inspection Review Documents

Section 2, General Firm Information

BCA: Obtain a copy of this section of the administrative inspection review.

Specialist: This section will be helpful if wanting to follow up on a response the firm had sent in.

- Gather any items in which sufficient information was not provided so it may be further investigated while at the firm.

7. Items from Other Sources

7.1 Past Inspection Reports

Specialist: Copy the last two In-depth Inspection reports that refer to the site of interest.

- Read previous inspection reports carefully. Previous reports and related correspondence contain important information about conditions previously found, especially the one immediately before the present one. A repeat violation within 6 months of written notification of the first infraction is prima facie evidence of willful violation (9 CFR 105.2). Note when and who conducted the previous inspection, exceptions found, and corrective actions that were taken.

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7.2 Open Investigations

Specialist: See the Investigations Manager, Biologics Compliance Inspector (BCI), or the Compliance Section Leader for information regarding open investigations.

- The BCI sends an email to the Team Leader of the inspection with open investigations for the relevant firm. The emails consist of information from the VBI dataset: VBI Number, the Specialist assigned to the VBI, the Alleged Violation, and the Last Status Update.
- The BCI also includes a listing of all regulatory actions taken on the firm. This information includes: The type of regulatory letter, the date it was sent, the regulation cited, product codes involved, and a brief description of the reason for the regulatory action.
- If another Specialist has opened an investigation regarding the selected firm, note this, and see if they request any information while at the firm.

7.3 Facility Documents

Specialist: Look at the blueprints and plot plans. The plot plan shows the layout of the establishment site. The plot plan legends identify the buildings and their principal uses. The building blueprints show the layout of the rooms within each building. The blueprint legends identify pieces of equipment and describe the procedures conducted and the agents that are processed in each room.

- Be sure all buildings for which blueprints are on file are shown on the plot plan. Identify all automatic-controlled equipment to check at the firm. Also note the filed date of each document and blueprint to verify that the CVB-IC and the firm copies are identical (see the current version of [ICFRM0001](#), *Pre-Inspection Blueprint Worksheet*).
- Analyze the facility documents for traffic patterns of people, media, and glassware movement, areas where vector control may be paramount, provisions for vector control, air flow patterns, sterility or sanitation control, and potential cross-contamination.
- Identify areas where contamination may occur; where products or agents might be accidentally mixed or switched; where particularly crucial steps of production are carried out. Note these on the worksheet. Be sure licensed and experimental products can be kept effectively separate.

Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

7.4 Production

Specialist:

- **Product Check-off Sheet.** Fill out a product check-off worksheet for each product to be examined (see the current version of [ICFRM0002](#), *Inspection Product Check-off Sheet*). The product license and permit license provides the true name, form, and code number for the product and the date the license was issued. The format is useful during later discussions with the licensee officials and also for referencing product information during inspections.
- **Outline of Production.** Carefully review the filed Outline of Production and the accompanying APHIS Form 2015 Transmittal Form (see **Appendix VII**). Note the date the outline was approved for filing (stamped). Note recent revisions. These may be pen-and-ink, page, or complete revisions. The outline guides required to organize production outlines are contained in 9 CFR 114.9 and VS Memorandum 800.206. An Outline of Production for a product is the best source of comprehensive information on preparation of the product. There is no simple way to demonstrate all the types of information that can be found through a careful review of an outline. However, some important parts are:

Parts I-IV. (Parts I. & II. of Allergenic Extracts) provide detailed information on the processing of the product. Here will be found information that may need to be cross-checked with Import Permits for Organisms and Vectors (9 CFR 122), lists of organisms (9 CFR 114.5), animal health records (9 CFR 117.3[b]), Animal Welfare Act records (9 CFR 1, 2, 3), preservatives, inactivating agents, etc.

Part V. provides information on the testing required to release individual serials for marketing. Determine if a visit to the CVB laboratory to learn more about specific tests is needed.

Part VI. (Part IV. for Allergenic Extracts) provides information on the sampling, packaging, and labeling of a product. It also gives information on storage and initial distribution of a product, plus uses, forms, dosages, expiration date determinations, and related information. Personnel may want to cross-check this information with label lists, sampler reports (APHIS Form 2020), inventory records, etc.

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7.5 Product Destruction

Specialist:

- Note any special product destruction procedures, permitted uses of approved landfills, or other information relating to environmental impact. CVB-IC must assure the discarded material is inactivated. Any other violations should be reported to the proper authorities.
- Identify serial lots, from the computer printout, that should be destroyed. Serials found satisfactory by the manufacturer and unsatisfactory by APHIS testing must be destroyed under APHIS supervision. APHIS Form 2045 (see **Appendix VIII**) is a certification showing serial lots destroyed under APHIS supervision.
- Serials that have been destroyed by the firm due to circumstances at the firm should be reviewed by the Specialist. The Specialist should review the records related to the serial and destruction of the serial.

7.6 Summary of Samples from Firm

Specialist: Go to the CVB laboratory and review selected APHIS Form 2020s (see **Appendix IX**) to determine if forms are correctly completed and signed by an authorized sampler. Sample numbers are assigned by the CVB laboratory.

7.7 General Correspondence and Special Files

Specialist:

- Go through the correspondence and other files for the licensee. These files contain a variety of information that may further identify items that may need special attention at the firm. Note information pertinent to the inspection. Be sure to verify that the information has not been superseded or countermanded.
- Review contents of the desk file. Desk files should contain no original records.
- Review pending APHIS Form 2008s which are filed for the firm.

7.8 *In vitro* References

BCA: Obtain a list of *In vitro*/Potency References for the firm located at:



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7.9 Customer Service Survey

BCA: Obtain one copy of the most current version of the Customer Service Survey and its corresponding letter. Include a pre-addressed stamped envelope with these documents.

Specialist: Provide this Survey and corresponding material to the firm's liaison.

8. Missing Documents

Contact the appropriate staff to arrange for replacing or obtaining copies of any required documents that are missing from office files.

9. Summary of Revisions

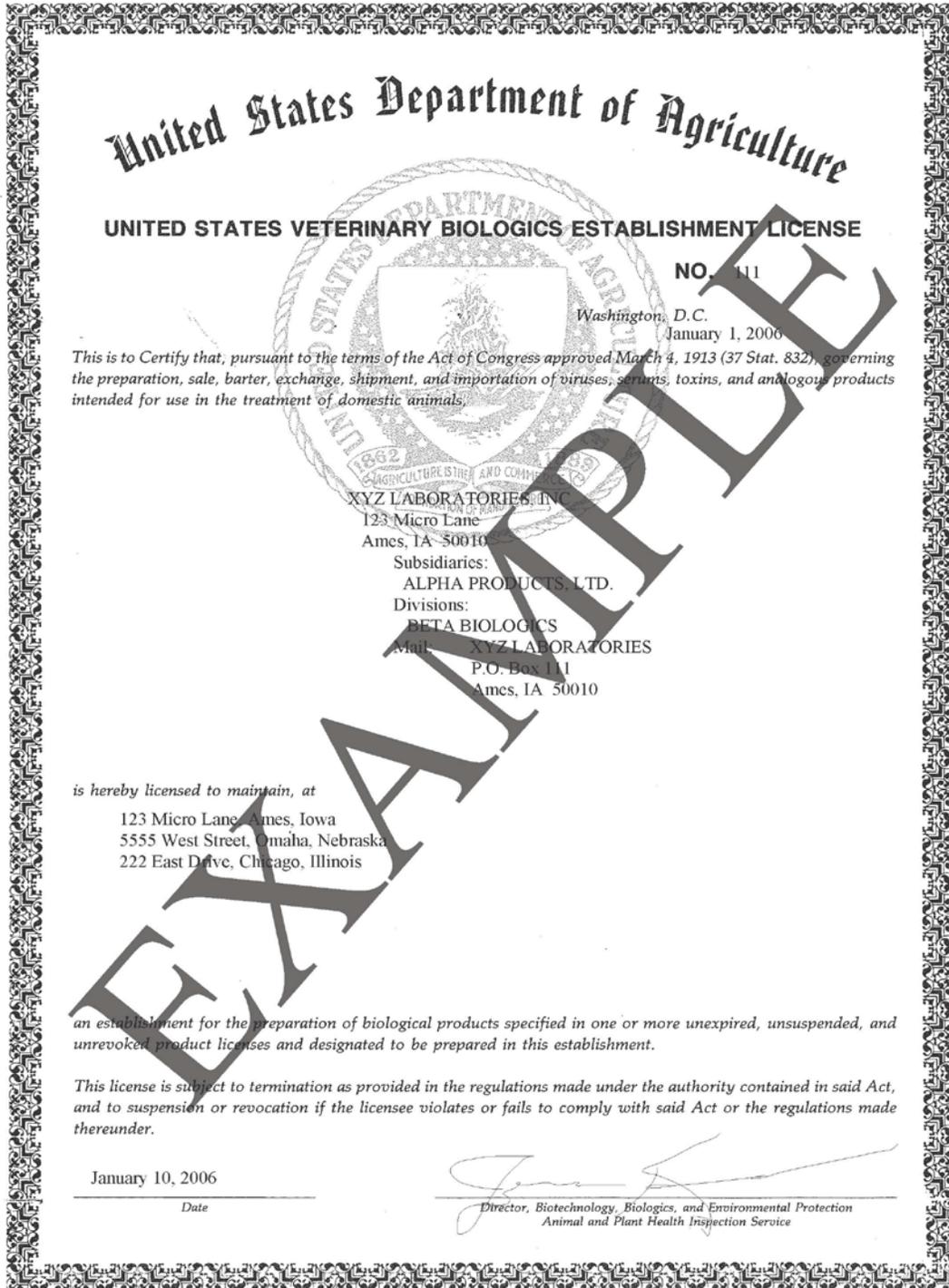
- The Contact information has been updated.
- **6:** This section has been updated to reflect more current information.
- **7.2:** This section has been deleted because Import Permits are no longer part of the PI Package.
- **7.9:** This section has been added to include the Customer Service Survey in the PI Package.

Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

Appendices

Appendix I

Figure 3A-1



United States Department of Agriculture

UNITED STATES VETERINARY BIOLOGICS ESTABLISHMENT LICENSE

NO. 111

Washington, D.C.
January 1, 2006

This is to Certify that, pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals,

XYZ LABORATORIES, INC.
123 Micro Lane
Ames, IA 50010

Subsidiaries:
ALPHA PRODUCTS, LTD.

Divisions:
BETA BIOLOGICS

Mail: XYZ LABORATORIES
P.O. Box 111
Ames, IA 50010

is hereby licensed to maintain, at

123 Micro Lane, Ames, Iowa
5555 West Street, Omaha, Nebraska
222 East Drive, Chicago, Illinois

an establishment for the preparation of biological products specified in one or more unexpired, unsuspended, and unrevoked product licenses and designated to be prepared in this establishment.

This license is subject to termination as provided in the regulations made under the authority contained in said Act, and to suspension or revocation if the licensee violates or fails to comply with said Act or the regulations made thereunder.

January 10, 2006

Date

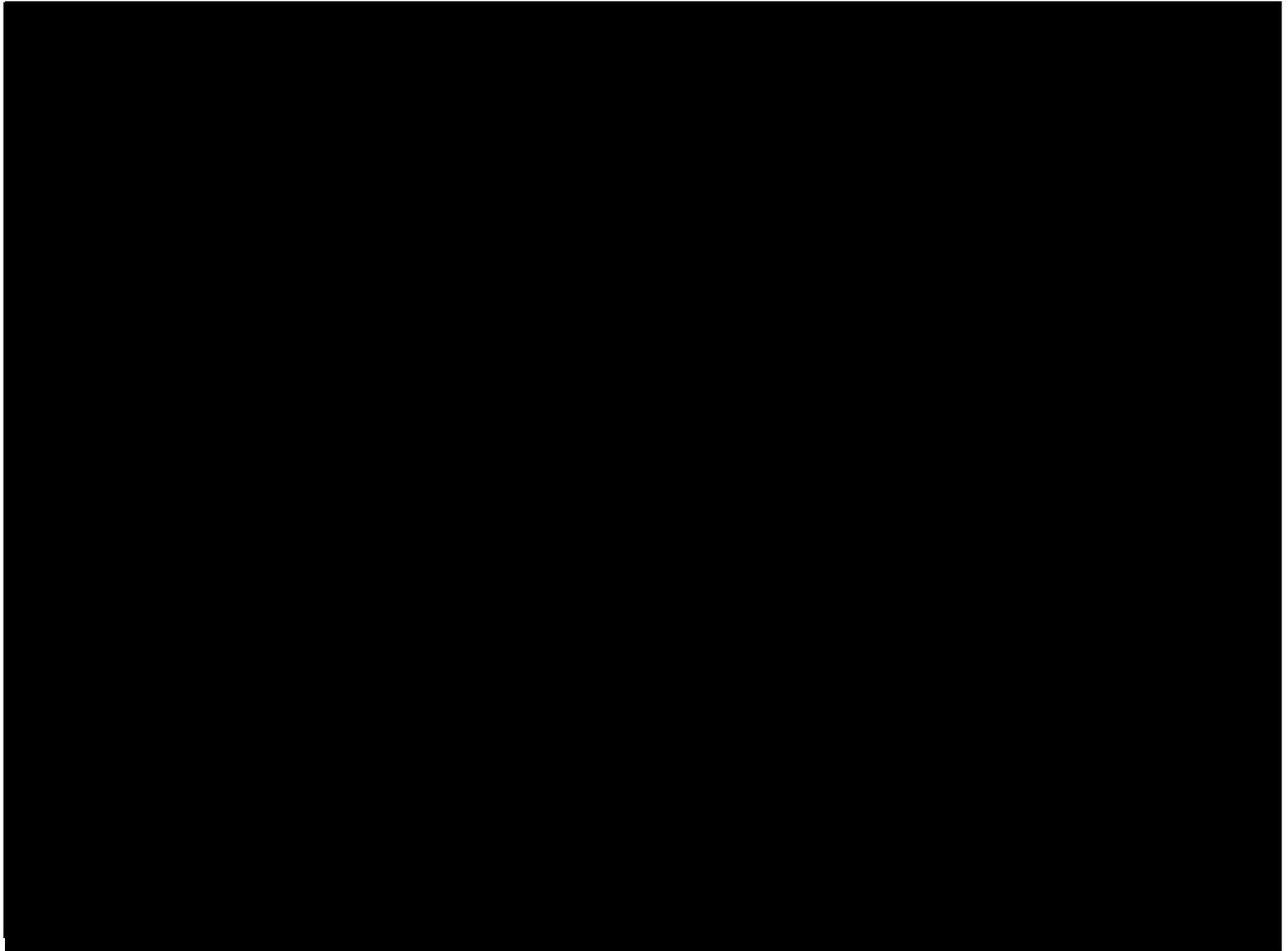
[Signature]
Director, Biotechnology, Biologics, and Environmental Protection
Animal and Plant Health Inspection Service

APHIS FORM 2002
(NOV 94)

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Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

Appendix II



Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

Appendix III

Figure 3A-2

**United States
Department of Agriculture**

UNITED STATES VETERINARY BIOLOGICAL PRODUCT LICENSE

Washington, D.C.,

This is to certify that, pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, the person holding United States Veterinary Biologics Establishment License No. _____ is authorized to prepare in the facilities designated in the establishment license:

CLOSTRIDIUM CHAUVOEI SEPTICUM BACTERIN

CODE A111.11

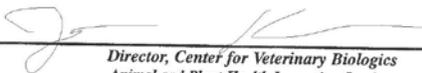
Preparation shall be in accordance with the provisions of the Act, the regulations made thereunder, and additional restrictions or requirements when listed below.

For Further Manufacturing

This license is subject to termination as provided in the regulations made under the authority contained in said Act, and to suspension or revocation if the licensee violates or fails to comply with said Act or the regulations made thereunder.

January 11, 2006

Date



Director, Center for Veterinary Biologics
Animal and Plant Health Inspection Service

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Appendix IV

Figure 3A-3

**United States
Department of Agriculture**

UNITED STATES VETERINARY BIOLOGICAL PRODUCT PERMIT

NO. 111

Issued at Washington, D.C. on
January 12, 2006
Expires
January 12, 2007

This permit is issued pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of veterinary biological products. So far as the jurisdiction of the U.S. Department of Agriculture is concerned,

ALPHA PRODUCTS, LTD.
5555 West Street
Omaha, Nebraska 11111

is authorized to import
Pastuerella Haemolytica - Multisida Bacterin, Code 2700.00

prepared by
Foreign Manufacturing, Inc.
987 Prince Edward Island, Canada

into the United States through the port of
Chicago, Illinois

Importation shall be made subject to the following special conditions:

This permit may be revoked if the permittee violates or fails to comply with said Act, the regulations made thereunder, or the conditions specified herein.

February 14, 2006
Date

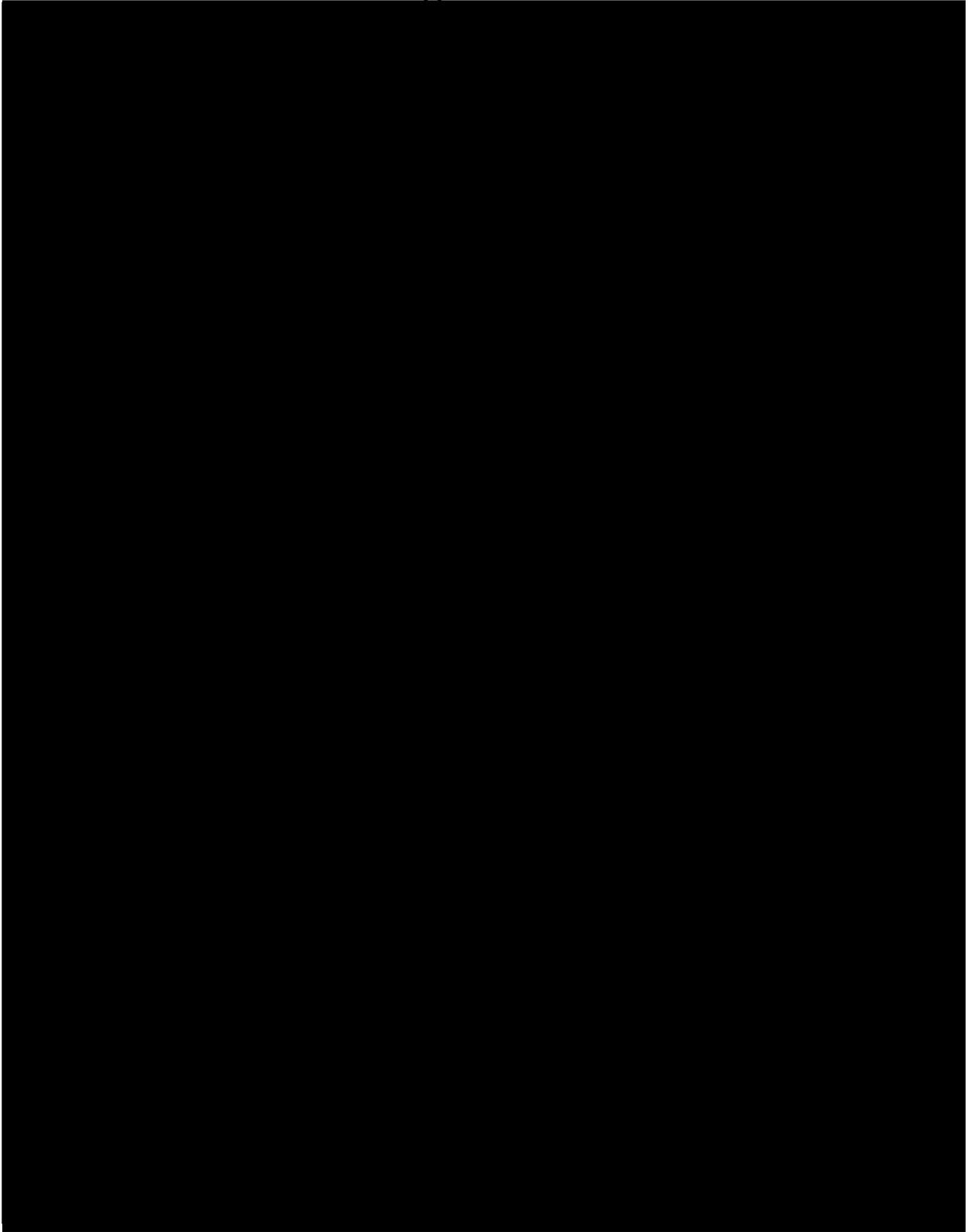

Director, Center for Veterinary Biologics
Animal and Plant Health Inspection Service

APHIS FORM 2006 (APR 2001)

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Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

Appendix V



Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

Appendix VII

Figure 3A-8

No U.S. Veterinary Biological Product license may be issued until product labels and circulars and outline of production have been reviewed (9 CFR 102, 112, and 114).
FORM APPROVED OMB NO. 0579-0013

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0013. The time required to complete this information collection is estimated to average .12 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE VETERINARY SERVICES CENTER FOR VETERINARY BIOLOGICS AMES, IOWA 50010 TRANSMITTAL OF LABELS AND CIRCULARS OR OUTLINES			1. NAME AND ADDRESS OF LICENSEE (Include Zip Code)			
NOTE: Submit original and 6 copies. Retain last copy.			3. ESTABLISHMENT LICENSE NO.	4. DATE SUBMITTED		
2. DATE OF PRIOR RELATED CORRESPONDENCE			5. NAME OF PRODUCT (Use separate form for each product)	6. PRODUCT CODE	7. "X" IF NEW PRODUCT <input type="checkbox"/>	
LABELS AND CIRCULARS SUBMITTED						
TYPE	FINISHED			SKETCHES		
	A. No. Sets	B. No. Copies of Each	C. Item on File Being Replaced (Give No. (s))	D. No. Sets	E. No. Copies of Each	F. Item on File Being Replaced (Give No. (s))
8. CONTAINER						
9. BOX						
10. CIRCULARS						
11. OTHER						
OUTLINE SUBMITTED (Do not submit with same form covering Labels and Circulars)						
12. NO. COPIES	13. TYPE OF SUBMISSION			14. PAGE NUMBERS AMENDED OR ADDED	15. DATE OF PREVIOUS OUTLINE	
	<input type="checkbox"/> New Outline	<input type="checkbox"/> Complete Revision	<input type="checkbox"/> Pages Amended	<input type="checkbox"/> Pages Added		
16. COMMENTS						
17. SIGNATURE OF LICENSEE REPRESENTATIVE			18. TITLE			
REVIEW BY VETERINARY BIOLOGICS						
EXCEPTIONS						
20. REVIEWED BY (Signature, Veterinary Biologics)					21. DATE RETURNED	

APHIS FORM 2015
(JAN 98)

Replaces APHIS Form 2015 (APR 89) which may be used.

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Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

Appendix VIII

Figure 3A-11

PRESS HARD - YOU ARE MAKING 3 COPIES - NO CARBONS REQUIRED

PRODUCT DESTRUCTION RECORD USDA-APHIS

1. NAME AND ADDRESS OF LICENSEE, PERMITTEE, OR OWNER (Street, city, state, and Zip Code) _____

2. LICENSE OR PERMIT NO. _____

3. DISPOSAL METHOD (Check "X" or specify)

SANITATION LANDFILL DRY HEAT
 AUTOCLAVE INCINERATOR

OTHER (Specify) _____

4. UNSATISFACTORY BIOLOGICAL PRODUCTS

PRODUCT NAME A	PRODUCT CODE B	SERIAL NO. C	CONTAINER SIZE D	NO. CONTAINERS DESTROYED E	REMARKS F

I certify that I witnessed the destruction of the products described above.

5. SIGNATURE _____ 6. TITLE _____ 7. DATE _____

APHIS FORM 2045 (FEB 90) Replaces VS Form 14-45 (FEB 75) which may be used.

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Appendix IX

Public reporting burden for this collection of information is estimated to average 50 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any aspect of this collection of information, including suggestions for reducing this burden, to the Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

This report is required by Regulation (9 CFR 113). Failure to report can result in no certification being made for authenticity of samples of product.
OMB NO. 0579-0013

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

SHIPMENT AND RECEIPT OF BIOLOGICS SAMPLES

INSTRUCTIONS: Submit original and one copy with samples. (Large carbons intact)

4. PURPOSE
 ROUTINE CONCURRENT SAMPLE MASTER SEED CELL LINE PRELICENSING SAMPLE
 RETENTION SAMPLE RESUBMISSION (Specify in remarks) OTHER (Specify in remarks)

5. HOW IS PRODUCT SHIPPED
 REFRIGERATED UNREFRIGERATED

PRODUCT NAME (No trade names)
(Only one entry per line) _____ 6. _____

PRODUCT CODE _____ 7. _____

1. DATE SUBMITTED _____ 2. FIRM LICENSE NO. _____

3. NAME AND MAILING ADDRESS OF FIRM (include Zip Code)

16. REMARKS

14. SIGNATURE OF AUTHORIZED GOVERNMENT SAMPLER _____ 15. DATE _____

17. CONDITION AND REMARKS _____

18. RECEIVED BY (Signature) _____

19. DATE RECEIVED _____

Telephone Number: () _____

ACKNOWLEDGMENT OF RECEIPT OF SAMPLES

APHIS FORM 2020 (Previous edition may be used)

Figure 3A-9

Review of Center for Veterinary Biologics Office Files for Pre-Inspection Packets

Appendix X

**Checklist for BCAs
List of Documents Needed for PI Package**

1. **Items from the [REDACTED]**
 - 1.1 Establishment [REDACTED]
 - 1.2 Product License [REDACTED]
 - 1.3 Product License [REDACTED]
 - 1.4 [REDACTED] Personnel
 - 1.5 Labels
 - 1.6 Trade Names
 - 1.7 Master Seeds and Master Cells
 - 1.8 FDA – Export Reform and Enhancement Act

2. **Items from [REDACTED]**
 - 2.1 [REDACTED] Report
 - 2.2 [REDACTED] Serials
 - 2.3 Special Test [REDACTED]
 - 2.4 Test Codes [REDACTED]

3. **Items from the Administrative Inspection Review Documents**
 - 3.1 General Firm Information (Section 2 of the AIR)

4. **Items from Other Sources**
 - 4.1 *In vitro* References
 - 4.2 Customer Service Survey