July 17, 2012

United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-15

TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Leadership Team

FROM: Richard E. Hill, Jr. */s/ Byron E. Rippke, for*
Director
Center for Veterinary Biologics

SUBJECT: Soliciting Input on Potential Form to Facilitate Requests to Ship Experimental Biological Product

I. PURPOSE

The purpose of this Notice is to solicit input from interested parties regarding a form for requesting shipment of experimental product. This Notice describes a form to streamline submissions requesting authorization to ship experimental product, as described in Title 9, Code of Federal Regulations (9 CFR), Part 103.3. The CVB will accept input on the form until September 1, 2012.

II. BACKGROUND

The Center for Veterinary Biologics (CVB) is currently evaluating methods to increase efficiency. One potential method is to develop a fillable pdf form that will facilitate requests to ship experimental biological product under 9 CFR 103.3. The single-page form serves as a cover application to which supporting documentation may be attached. It also contains a checklist to assist in assembling a complete submission. The bottom of the form contains space for the CVB to authorize product shipment.

The use of the form, although voluntary, should reduce a firm's time in creating a request. Since it contains prompts for all required supporting documentation, it should reduce the number of incomplete submissions that require amendments. The form will also decrease the time needed for the CVB to prepare a regulatory response.

III. ACTION

The CVB is soliciting input from industry regarding the content and usability of the attached draft form. We also welcome stakeholder opinion regarding the potential use of

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standard forms for other common submissions. Comments may be sent to the CVB at the address shown in the left margin above or may be emailed to CVB@aphis.usda.gov until September 1, 2012.

IV. IMPLEMENTATION/ APPLICABILITY

If the CVB receives favorable feedback, this form will be forwarded to the Office of Management and Budget (OMB) for approval under the Paperwork Reduction Act of 1995. Upon OMB approval, this form will be available on the Biologics Forms page of the Veterinary Biologics portion of the APHIS website at http://www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml.

Attachment

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According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. **This form is currently being considered for submission to the OMB.** The time required to complete this information collection is estimated to average 1 hour 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.

OMB Approval Pending

DRAFT

This application may be submitted to request authorization to ship experimental biological product, as specified in 9 CFR 103.3. **INSTRUCTIONS:** See reverse side.

U.S. DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES, CENTER FOR VETERINARY BIOLOGICS

APPLICATION FOR AUTHORIZATION TO SHIP EXPERIMENTAL VETERINARY BIOLOGICAL PRODUCTS

1. NAME AND FULL MAILING ADDRESS OF APPLICANT

2. U.S. VET. EST. NO. (if applicable)

3. APPLICATION TYPE: ☐ NEW ☐ AMENDMENT
TO SUBMISSION DATED_____
AND/OR PRIOR CVB MAIL LOG ID_____

4. PRODUCT(S) TO BE SHIPPED **(CHECK HERE ☐ IF ADDITIONAL PRODUCT INFO APPENDED)**

A. BIOLOGICAL PRODUCT TRUE NAME OR DESCRIPTION	B. PROD CODE	C. SERIAL/LOT ID(s)	D. MAX QTY
	☐ UNL ☐ LIC		
	☐ UNL ☐ LIC		

5. RECIPIENT(S) **(CHECK HERE ☐ IF ADDITIONAL RECIPIENT INFO APPENDED)**

A. NAME AND SHIPPING ADDRESS	B. LOCATION OF PRODUCT USE (IF DIFFERS FROM 5A)

CHECKLIST FOR SUPPORTING MATERIAL

ITEM	DESCRIPTION	A. WITH THIS APPLICATION ("X")	B. DATE OR CVB MAIL LOG ID OF PREV SUBMISSION
6. METHOD OF PRODUCTION	☐ OUTLINE OF PRODUCTION (9CFR 114.9) ☐ EQUIVALENT		
7. PRODUCT TEST RESULTS	☐ APHIS FORM 2008 ☐ EQUIVALENT		
8. PERMIT OR LETTER OF PERMISSION FROM AUTHORITIES IN EACH STATE/FOREIGN COUNTRY	LIST STATE(S) OR FOREIGN COUNTRY:		
9. STUDY PROTOCOL NO. _____	☐ PIVOTAL USDA LICENSING STUDY ☐ EXPLORATORY ☐ FOR INTERNATIONAL REGISTRATION		
10. DISTRIBUTION OF PRODUCT AMONG MULTIPLE RECIPIENTS (if applicable)			
11. EXPERIMENTAL LABELS (2 copies)			
12. DATA TO DEMONSTRATE WHOLESOMENESS OF MEAT (if applicable)			
13. OTHER			

14. DISPOSITION OF UNUSED PRODUCT: ☐ DESTROY ON-SITE ☐ RETURN TO APPLICANT ☐ OTHER (describe)_____

15. DISPOSITION OF STUDY ANIMALS: ☐ EUTHANASIA & DISPOSAL ON-SITE ☐ RETURN TO OWNER ☐ SLAUGHTER NO LESS THAN _____ DAYS AFTER FINAL PRODUCT USE

I agree to ship this experimental product in accordance with 9 CFR 103.3 and conduct the study according to the filed protocol, also observing any additional conditions imposed by the State or foreign country in which the study will be conducted. I agree to furnish, upon request, additional information concerning meat animals prior to moving these animals from the test premises. Upon conclusion of the studies, I agree to summarize the results and submit them to APHIS.

16. PRINTED NAME AND TITLE OF APPLICANT	17. SIGNATURE OF APPLICANT	18. DATE SUBMITTED (MM/DD/YYYY)

FOR VETERINARY BIOLOGICS USE ONLY

The applicant is authorized to ship the above experimental product to the designated recipients to conduct the specified study, with the Exceptions listed in Item 19. In the event the product is compromised during shipment, one repeat shipment may be made. This authorization is effective for one year from the date in Item 21. If a pivotal USDA licensing study protocol was submitted with this application, comments on the study will be returned under separate cover. Other protocols are filed for information only, unless CVB comments are explicitly requested. Date-stamped copies of experimental labels are enclosed.

19. EXCEPTIONS

20. APPLICATION APPROVED BY (Signature)	21. DATE APPROVED	22. CVB MAIL LOG NO.

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INSTRUCTIONS FOR COMPLETING THIS FORM:
Submit one copy of the form. Enclose one copy of each supporting document, except for labels (Line Item 12). If additional space is needed, attach additional sheets and refer to Item No.

If APHIS's Center for Veterinary Biologics (CVB) approves the request, the CVB will complete items 19-22 and return the form to the applicant.

1. NAME AND FULL MAILING ADDRESS OF APPLICANT
Enter the establishment name and complete mailing address (street, city, state, ZIP) of the applicant. If the applicant has been assigned a veterinary biologics establishment number by APHIS, enter the mailing address on file with APHIS. The processed form will be returned to this address.

2. **U.S. VETERINARY ESTABLISHMENT NUMBER**
Enter the veterinary biologics establishment number assigned by APHIS, if one has been assigned.

3. APPLICATION TYPE
Indicate whether this is a new request or an amendment to a prior authorization. If it is an amendment, enter the submission date and, if known, the CVB mail log number of the prior submission. The CVB mail log number appears in Item 22 of all processed forms.

4. PRODUCT TO BE SHIPPED
A. True Name or Description: Enter the True Name designated by APHIS, if applicable. Otherwise provide a clear description of the product; avoid acronyms or internal working names.
B. Product Code: Enter the Product Code assigned by APHIS, if applicable. Otherwise, enter NA. Check whether the product is currently licensed by the USDA (LIC). Select UNL if the product is currently in the USDA licensing process, is not yet under consideration for licensure, or is not intended for licensure.
C. Serial or Lot Number: Enter the unique lot identification for the product batch being shipped. If more than one lot of the same product is being shipped, it is permissible to enter more than one identification per line.
D. Maximum Quantity to be Shipped: Enter the maximum quantity of each serial to be shipped. Indicate the unit of measure (e.g., mL, doses, number of kits or tests).

If more than 2 distinct products are being shipped, attach a sheet with the requested information for the remaining products and check the box on the form to indicate there is an additional sheet..

5. RECIPIENT
A. Name and Shipping Address: Enter the name, affiliation, and complete shipping address of each recipient of the experimental product.
B. Location of Product Use: If the study location differs from the shipping address, specify the study location(s). Otherwise, enter NA.

If there are more than 3 recipients, attach a sheet with the requested information, and check the box on the form to indicate there is an attached sheet.

CHECKLIST OF SUPPORTING MATERIAL
Items 6-11 and 14-16 in the checklist should be addressed for every application. Items 12-13 should be provided as applicable. If supporting information is attached to, or provided concurrently with, the application, place an X in column A of the corresponding item. If the information was provided previously, it is permissible to cite the submission date and/or CVB Mail Log Number of the previous submission in lieu of providing another copy.

6. METHOD OF PRODUCTION
Clearly explain how the experimental product was made. The most efficient means is to provide an Outline of Production, formatted according to 9 CFR 114.9. If an Outline is not available, provide information equivalent to that captured in an Outline of Production.

7. PRODUCT TEST RESULTS
The minimum testing required for products to be administered to animals is sterility or purity testing; additional tests may be required by APHIS depending on the nature of the product and the study purpose. If the product is licensed or in the USDA licensing process, provide the results of tests described in Section V of the Outline of Production. Ideally submit these results on APHIS Form 2008, but an equivalent document is acceptable. For exploratory studies unrelated to product licensing, also provide a summary of preliminary research work.

8. PERMIT OR LETTER OF PERMISSION FROM AUTHORITIES IN EACH STATE/FOREIGN COUNTRY
Authorization must be obtained from each state and foreign country described in Items 5A and 5B. If vaccinated animals are moved across State lines, obtain authorization from each State involved. Attach a copy of each State authorization or acknowledgement letter. Attach a copy of the import permit for each foreign country. If no import permit is required, attach a document stating this.

9. STUDY PROTOCOL
Attach a study design/protocol for the *in vivo* work to be performed with the experimental product. Ensure that the protocol clearly states the biocontainment level under which the work will be conducted.

If the protocol has a unique study identifier, enter it in the blank indicated. Check whether the study is a pivotal USDA licensing study, an exploratory (non-pivotal) study, or is being conducted solely to support international registration. The CVB conducts in-depth reviews and provides comments on pivotal USDA licensing study protocols. Unless otherwise requested, exploratory and international registration study protocols are filed for information without return comments.

10. DISTRIBUTION OF PRODUCT AMONG MULTIPLE RECIPIENTS
If the experimental product is to be distributed among multiple recipients, attach a document listing the quantity of each serial(s) to be provided to each recipient.

11. EXPERIMENTAL LABELS
Submit two copies of each of the labels that will be shipped with the experimental product. Format the labels according to 9CFR 103.3(d). Avoid acronyms and abbreviations in the product name.

12. DATA TO DEMONSTRATE WHOLESOMENESS OF MEAT
If the study is being conducted in meat animals and the study animals will be sent to slaughter for human consumption after participating in the study, attach information (such as residue clearance data) to demonstrate that the meat from the study animals should be wholesome.

13. OTHER
APHIS may request additional information to support applications for certain products or to conduct certain types of studies. If applicable, briefly describe the purpose of the additional information in the line provided and attach supporting documentation.

14. DISPOSITION OF UNUSED PRODUCT
Specify how the recipient will dispose of unused product when the study is completed. If more than one method is selected, attach a sheet explaining how the product is divided.

15. DISPOSITION OF STUDY ANIMALS
Specify how surviving study animals will be handled at the conclusion of the study. If more than one method is selected, ensure that the study protocol explains how the animals are divided or attach a separate sheet with this information. This Item does not apply to *in vitro* diagnostic test kits.

16. PRINTED NAME AND TITLE OF APPLICANT
If the applicant has been assigned a U.S. veterinary biologics establishment number, the APHIS primary or alternate liaison should serve as the applicant.

17. SIGNATURE OF APPLICANT
Self-explanatory

18. DATE SUBMITTED
This date should correspond to the date the application is mailed. This will be the submission date cited in all return correspondence. Format as MM/DD/YYYY.

THE FOLLOWING ITEMS ARE FOR VETERINARY BIOLOGICS USE ONLY

19. EXCEPTIONS
If APHIS identifies any exceptions or special circumstances regarding the authorization to ship experimental product, they will be noted here.

20. APPLICATION APPROVED BY
Signature of the APHIS-CVB official approving the application. If an application is denied, the form will not be signed and reasons for denial will be communicated in enclosed correspondence.

21. DATE APPROVED
Self-explanatory. Shipment of experimental product should not occur prior to this date.

22. CVB MAIL LOG NUMBER
The application is assigned a unique tracking number when received by APHIS. For improved efficiency, cite this number in future communications regarding this application.

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