



May 13, 2005

United States
Department of
Agriculture

VETERINARY SERVICES MEMORANDUM NO. 800.87

Animal and Plant
Health Inspection
Service

Subject: Guidelines for Licensing Establishments with Separated Premises

To: Veterinary Services Management Team, Biologics Licensees, Permittees, and Applicants Directors, Center for Veterinary Biologics

Washington, DC
20250

I. PURPOSE

This memorandum provides guidance for licensing two or more separate premises as one establishment under the provisions of 9 CFR 102.4.

II. CANCELLATION

This memorandum cancels Veterinary Biologics Memorandum No. 800.87 dated August 23, 1999.

III. GENERAL

The regulations in 9 CFR 102.4 prohibit the Animal and Plant Health Inspection Service (APHIS) from issuing an establishment license unless, in the opinion of the Administrator, the establishment can be operated in compliance with the Virus-Serum-Toxin Act (VSTA). The regulations in 9 CFR 115 authorize APHIS inspectors to inspect licensed facilities and products to determine whether they comply with the VSTA and regulations. It is APHIS policy to inspect all licensed premises of an establishment that are used for preparation, testing, and distribution of veterinary biologics. When premises separated by a great distance are listed on the same establishment license, there may be problems in carrying out these inspections at the same time to determine compliance with the VSTA. These guidelines establish criteria for documenting activities and maintaining records to address these problems and permit APHIS to inspect under such conditions.

IV. GUIDELINES

APHIS will consider the licensing of two or more remotely located premises as one establishment under the following conditions:



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- A. Responsibility for Operations - Each licensed establishment must have one person legally responsible for all activities at all premises listed on the establishment license. This person will sign the APHIS Form 2001, Application for United States Veterinary Biologics Establishment License, listing all the sites for the establishment.
- B. Mailing Address - The licensed establishment should have one mailing address for all government correspondence as listed on the establishment license.
- C. Government Liaison - Each licensed establishment must have one government liaison representing all premises listed on the establishment license. This liaison is responsible for and should handle all government submissions and correspondence and will coordinate inspection activities and compliance. The licensee will designate a site contact that is approved by the Center for Veterinary Biologics, (CVB) to coordinate compliance and unannounced inspections at locations beyond a reasonable travel time from the normal location of the liaison.
- D. Serial Release - One person representing the licensed establishment should be responsible for control of serial release submissions. APHIS will report serial releases for all products to that person at the mailing address listed on the establishment license.
- E. Submission of Serials and Serial Records for Release - In the event of an establishment purchase, sale or other consolidation, veterinary biologics will maintain the establishment number and product code identification of the first submission received by CVB for a given serial. If an APHIS Form 2008, serial reprocessing request, extension of dating, inventory correction, or samples listing one of the two original establishment numbers are submitted before the firms are consolidated, the serial will keep this original identification throughout dating and any other post release actions such as reprocessing, rebottling or extension of dating.

New serials (including samples) and serial records submitted for the first time after the new or consolidated establishment license has been issued will have the identification of the new combined establishment.
- F. Records - All premises listed on the establishment license must use the same system to maintain and retain records. This includes the record keeping system for serial assembly and subsequent handling. The licensee should maintain the original copies of records at the premises where the activity occurs.
- G. Official Documents - The licensee must maintain appropriate CVB approved plot plans, blueprints, legends, outlines of production, labels and other official documents at each premises for use by APHIS inspectors. A controlled copy of each applicable currently approved document is acceptable for sites other than the site where the official liaison is located.

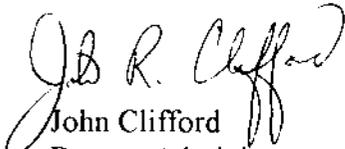
- H. Movement of Biological Materials Between Premises - The plot plan legend must describe how materials move between premises. Materials include component parts to be combined to form a biological product, all biological products in the course of preparation, and all completed biological products. It also must describe the precautions taken to protect such materials during movement between premises. Firms should identify and describe the mode of transportation for such materials in the plot plan legend as they would describe a piece of equipment such as a cooler. The plot plan legend should also describe how such materials move between the mode of transportation and the production or in-process cooler. Firms should revise their plot plan legends as necessary to ensure that they include all such materials being moved and all current procedures being used for movement of the materials between sites.
- I. Transfer Documents - Firms must use transfer documents to certify that they are following the procedures established to ensure product protection during movement between premises. The records should show how and when periodic checks are conducted on refrigeration equipment and temperature recording devices used in such transfers to ensure proper temperatures are being maintained.
- J. Distribution Centers – Distribution centers that are wholly owned and controlled by a firm licensed to produce veterinary biologics may be included on the establishment license. These sites will be subject to APHIS inspections to determine whether they comply with the VSTA and regulations.
- K. Licensing Documents – Within one year of the date when premises previously licensed as separate establishments are consolidated and licensed as one establishment, the firm must resubmit official Outlines of Production, labels, plot plans, legends, blueprints, and other documents to reflect the change.

During the first year, the documents on file will be used to determine compliance with the VSTA and regulations. Outlines of Production should specify the premises where production will occur and APHIS Form 2007s should indicate the site where the employee works.

- L. Technology Transfer – When firms transfer the production or testing of veterinary biologics from one location to another, appropriate records must be maintained of the training and process of transferring the production or testing. The CVB must be notified of this movement prior to final production or testing occurring at the new location. The CVB may test serials prepared or tested at the new location. The records of the technology transfer must be maintained for review by CVB during the next in-depth inspection or be made available for review if requested by CVB.

V. EXCEPTIONS

Premises previously exempted from appearing as production facilities on establishment licenses are not subject to this memorandum. Examples of such premises are irradiation facilities and milk collection and assembly points.


John Clifford
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Veterinary Services