



Animal and Plant
Health Inspection
Service

Veterinary Services

1400 Independence
Ave, SW

Washington, DC
20250

VETERINARY SERVICES MEMORANDUM NO. 800.63

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

FROM: Jack A. Shere
Deputy Administrator

SUBJECT: Personnel at Licensed Establishments

I. PURPOSE

This memorandum provides guidance concerning the official liaison and biographical summaries required under title 9, *Code of Federal Regulations* (9 CFR), section 114.7(a).

II. REPLACEMENT

This memorandum replaces Veterinary Services (VS) Memorandum No. 800.63 dated October 1, 1999. It is being updated to include guidance for designated roles within the National Centers for Animal Health (NCAH) Portal for electronic submissions to the Center for Veterinary Biologics (CVB).

III. BACKGROUND

- A. Personnel responsible for any phase of development, manufacture, or distribution of a veterinary biological product must provide evidence to the CVB that they are competent to produce a consistent quality product that is pure, safe, potent, and effective. Competency may be supported by education, training, and/or experience.
- B. For the purpose of this memorandum, the following definitions apply:
 1. Biographical Summaries: Information submitted to the CVB to support personnel competency. "Contact and Qualifications of Veterinary Biologics Personnel," APHIS Form 2007, meets the requirement.
 2. NCAH Portal: Web-based submission system. The NCAH Portal Website address is <https://ncahappspub.aphis.usda.gov/NCAHPortal/public/>.

IV. GUIDELINES FOR QUALIFICATION OF VETERINARY BIOLOGICS PERSONNEL

A. Official Liaison and Alternate(s)

1. Each licensee or permittee must designate a person to act as his or her official liaison for formal communication with the CVB, as provided under 9 CFR 114.7(a).
 - a. The liaison is considered to be responsible for communicating the licensee/permittee's regulatory needs to the CVB to obtain and maintain the establishment license and product licenses or permits.
 - b. The liaison may designate alternates. The number of alternate liaisons should accurately reflect the need of the firm and not be excessive. Liaisons must periodically review the list of alternate liaisons and adjust the number as needed.
 - c. Prior to engaging in formal communication on behalf of the regulated entity, the CVB will acknowledge the role of liaison and alternate liaison.
 - d. The liaison must have adequate knowledge of the day-to-day activities of the licensee or permittee.
 - e. Liaisons and alternate liaisons must reside in the United States. Site contacts may be named for international manufacturing sites or multiple domestic sites if needed.
 - f. Liaisons and alternate liaisons must have a physical address represented on the establishment license.
 - g. Typically, consultants are not appropriate to be named as the liaison.
2. Official correspondence from the CVB will be sent to the liaison at the official mail address as listed on the U.S. Veterinary Biologics Establishment License or returned via the NCAH Portal.

Liaisons do not need to reside at the physical location of the official mail address, as long as there are processes in place to timely route correspondence to the liaison.

3. The biographical summary included on the APHIS Form 2007 for the liaison, or alternate liaison must be filled out completely, including information related to employee education. Employee education may include degrees obtained at

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secondary educational institutions, as well as formal training certificates relevant to the liaison function.

4. The official liaison or the alternate is responsible for signing the following documents:
 - a. Official correspondence initiated by the licensee or permittee.
 - b. Requests for exemptions, exceptions, or authorizations.
 - c. Responses to official letters from the CVB.

B. Other Biographical Summaries. An APHIS Form 2007 used to obtain the qualifications of supervisory personnel must be submitted for each employee who has final responsibility for one or more of the following functions in a licensed establishment. These employees may or may not have portal access. An APHIS Form 2007 should be filed for employees involved in the following functions:

1. Research and product development.
2. Product manufacture including, but not limited to:
 - a. Management of seed and cell cultures.
 - b. Incoming review of raw ingredients.
 - c. Inoculation through harvest processes, including in-process testing.
 - d. Downstream processing.
 - e. Batching/blending of serials.
 - f. Filling.
 - g. Labeling and packaging.
 - h. Storage and distribution.
3. Quality control.
4. Acquisition, maintenance, use, and disposal of animals.
5. Authorized sampler (see VS Memorandum No. 800.59 for further information), including:
 - a. Selection, shipment, and retention of samples.
 - b. Personnel signing and submitting APHIS Form 2020, "Shipment and Receipt of Biologics Samples."
6. Serial Release (see VS Memorandum No. 800.53 for further information), including:
 - a. Personnel signing and submitting APHIS Form 2008, "Veterinary Biologics Production and Test Report."

V. NCAH PORTAL REQUIREMENTS

The NCAH Portal is used to electronically submit data to and receive responses from the CVB.

- A. Each employee must have USDA Level 2 eAuthentication. Detailed instructions are located at <https://www.eauth.usda.gov>.
- B. Each employee must have an APHIS Form 2007 on file with the CVB.
- C. Once employees have provided the CVB with a USDA Level 2 eAuthentication ID and have an APHIS Form 2007 on file with the CVB, they may enter and edit information regarding their own APHIS Form 2007.
- D. Additional NCAH Portal roles and authorities related to the CVB may be found at www.aphis.usda.gov/animal_health/vet_biologics/publications/2-PortalRoles.pdf.

VI. IMPLEMENTATION/APPLICABILITY

- A. Instructions for completing a hard-copy APHIS Form 2007 can be found on page 2 of the form.
- B. Submit all APHIS Forms 2007 to CVB-Inspection and Compliance (IC). The CVB-IC will be responsible for routing forms within the CVB, whether submitted by hard copy or through the NCAH Portal.
- C. The changes contained in this memorandum are effective immediately.