

October 1, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.63

Subject: Personnel at Licensed Establishments

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

I. PURPOSE

This memorandum provides guidance concerning the official liaison and biographical summaries required under the provisions of 9 CFR 114.7(a).

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.63 dated March 30, 1984.

III. GUIDELINES

A. Official Liaison and Alternate(s)

Each licensee or permittee must designate a person to act as their official liaison to make contacts with the Center for Veterinary Biologics (CVB). Up to three alternate liaisons may also be designated. CVB addresses all official mail to the official liaison. The official liaison or an alternate is responsible for signing the following documents:

1. Official Correspondence - Official correspondence initiated by the licensee or permittee.
2. APHIS Forms 2015 - Transmittal forms for labels and circulars or Outlines of Production.
3. Letters of Transmittal - Letters of transmittal for documents submitted in support of licensure or revisions of labels and outlines.
4. Requests for Exemption or Authorization - Requests for special exemption or authorization such as reprocessing requests, field trials, and extensions of dating.

5. Response to Official Letters From CVB - Official letters regarding inspection findings, consumer complaints, Center for Veterinary Biologics-Laboratory test results, or other regulatory actions.

B. Biographical Summaries

An APHIS Form 2007, 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:

1. Official Liaison and Alternate(s).
2. Research and Product Development.
3. Product Manufacture Including:
 - a. Preparation, maintenance, and selection of seed cultures;
 - b. Preparation of equipment, media, substrates, and additives;
 - c. Inoculation, incubation, and harvest, including collection of in-process test samples;
 - d. Pooling, filling, and capping;
 - e. Operation of lyophilization equipment;
 - f. Labeling and packaging; and
 - g. Storage and initial distribution.
4. Quality Control Testing, Including Sample Selection.
5. Acquisition, Maintenance, Use, and Disposal of Animals.
6. APHIS Forms 2008 - Preparation of Veterinary Biologics Production and Test Reports.

7. APHIS Forms 2002 - Shipment and Receipt of Biologics Samples.
8. Selection of Official Government Samples - Authorized samplers.

/s/

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Veterinary Services