



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 17-11

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

FROM: Byron E. Rippke
Director

SUBJECT: Facility Documents Processing Changes – Pilot Project

I. PURPOSE

The Center for Veterinary Biologics (CVB) has evaluated the processing of facility document submissions as a part of a business process improvement project. The proposed outcome has been to reduce the CVB resources needed to process incoming facility document submissions and to reduce the time to respond to these submissions, while ensuring that the review performed by CVB on each facility document submission is thorough and complete.

II. BACKGROUND

Baseline data have been collected as a part of this business process improvement to provide benchmark measurements for the revised process. The revision of Veterinary Services (VS) Memorandum 800.78, Preparation and Submission of Facilities Documents, dated August 18, 2017, and the development of a single-page form for submission and processing facility documents are expected to increase both the quality and consistency of facility document submissions and result in a decreased response time by the CVB for each submission.

The CVB review and processing of facility documents will focus on ensuring licensees and permittees have provided sufficient information, especially regarding the function of each room and the precautions taken to assure product quality and safety.

III. ACTION

The CVB will conduct a pilot project using revised VS Memorandum 800.78 and the draft Facility Document Submission Form (FDS) and encourages all licensees and permittees to participate.

The CVB-Inspection and Compliance has developed an FDS that is currently under review by the Office of Management and Budget. A draft of the FDS and instructions for use are attached to this Notice and should be used during the pilot project.

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CVB will also be instituting a practice of auditing back the submission if the facility documents are incomplete and do not meet the basic facility requirements as listed in title 9, *Code of Federal Regulations* (9 CFR), part 108. Examples of this include, but are not limited to, no signature of the responsible official on the plot plan or blueprint or no compass points shown.

The CVB response to the facility document submission will be marked on the bottom portion of the FDS and returned to the establishment with the facility documents. Responses will be one of the following:

[A] Documents Filed indicates the submission has been accepted with no revisions necessary.

[B] Documents Filed, Revisions Requested indicates the submission has been accepted with changes required to be made at the next revision. A listing of issues with the applicable 9 CFR reference will be sent back to provide guidance.

[C] Documents Returned indicates the submission is insufficient for filing. A listing of issues with the applicable 9 CFR reference will be sent back to provide guidance. But note, this listing may be incomplete as the review will cease if several items are not in compliance with the regulations. This would be an indication the quality review at the establishment was not adequate. This action would also be used for submissions that are audited back as incomplete.

IV. IMPLEMENTATION/APPLICABILITY

The pilot project will be in effect for 2 months upon publication of this Notice for all licensees and permittees (including both quarantine sites and foreign manufacturing sites). It would also be beneficial for establishments in the pre-licensing phase of licensure or permit approval to use this process. During the 2-month pilot project, the CVB will be evaluating the revised process and gathering data. Updates to the process may be implemented at the end of the pilot project.