



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE 20-02

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

FROM: Byron Rippke
Director

SUBJECT: NCAH Portal Functionality: Electronic Labeling Submission Revision

I. PURPOSE

The purpose of this Notice is to inform licensees, permittees, and applicants that the Center for Veterinary Biologics (CVB) is revising and adding a new type of document for the label mounting sheet for label submission in the NCAH Portal under APHIS Form 2049. Licensees, permittees, or applicants must be NCAH Portal enabled to submit an electronic label.

II. BACKGROUND

The NCAH Portal is external-facing and enables web-based electronic submissions and responses between biologics licensees, permittees, applicants, and the CVB. Submission of electronic labels via the NCAH Portal has been available since 2016 using only a Microsoft Word template for the label mounting sheet. This revision updates the Word version of the label mounting sheet for submission through the NCAH Portal and provides an additional label mounting sheet in Adobe PDF form.

III. ACTION

A. NCAH Portal-Specific Format and Submission Process Required

The procedure for submitting and reviewing electronic labels is substantially different from the traditional paper process. It leverages efficiencies of electronic document comparison and document navigation. Therefore, it is essential to submit labels in the proper electronic format.

Before submitting an electronic label, read the following instructions:

- Revised User Guide 11—Submitting Labels to CVB-Policy, Evaluation and Licensing
- Revised User Guide 13—Using the CVB Template for a Label Mounting Sheet
- The WORD template Label Mounting Sheet under User Guide A has been revised.
- A PDF template Label Mounting Sheet is now available under User Guide C.

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The procedure includes:

- Document preparation of each label on a CVB-approved electronic template Label Mounting Sheet.
- Submission of additional documents to support labeling, such as correspondence or translations, as Incoming-Other.

Direct any additional questions to CVB.PIMS@usda.gov.

B. Staged Submissions

Please submit no more than five electronic labels in one submission.

IV. IMPLEMENTATION/ APPLICABILITY

Detailed procedural instructions, and NCAH Portal user guides, will be available April 1, 2020, on the NCAH Portal Guidance page of the APHIS CVB website. Users are expected to read and understand User Guides 11 and 13 *prior to* submitting electronic labels.

The CVB will continue to process paper labels for those products that do not yet have an electronic approved label on file with the CVB, but once converted to electronic format, only electronic revisions will be accepted.

Electronic submission via the NCAH Portal is strongly encouraged.