Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 19-10

TO: Biologics Permittees

Directors, Center for Veterinary Biologics Veterinary Services Leadership Team

FROM: Byron Rippke

Director

SUBJECT: Expanded NCAH Portal Functionality: APHIS Form 2005

Applications for Sale and Distribution

I. PURPOSE

The purpose of this Notice is to inform permittees the Center for Veterinary Biologics (CVB) is expanding the functionality of the web-based NCAH Portal by accepting submission of APHIS Form 2005 applications marked for Sale and Distribution. Submitters must be NCAH Portal-enabled to submit electronic APHIS Form 2005 applications.

II. BACKGROUND

The NCAH Portal is external-facing and enables web-based electronic submissions and responses between biologics firms and CVB. This expands NCAH Portal submissions to the Policy, Evaluation and Licensing (PEL).

III. ACTION

Beginning in September 2019, all active permittees will be able to submit APHIS Form 2005 applications for General Sale and Distribution to apply for a change in the quarantine site or new products from the same foreign manufacturer through the NCAH Portal. Submit APHIS Form 2005 applications for a new foreign manufacturing site by paper, as the new permit number does not exist. Before submitting an APHIS Form 2005 application, read the following instructions on the NCAH Portal Guidance page of the CVB website.

• User Guide 29—APHIS Form 2005 Application for United States Veterinary Biological Product Permit: Sales & Distribution

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

IV. IMPLEMENTATION

Implementation of the NCAH Portal for APHIS Form 2005 is scheduled to begin September 26, 2019, for all active permittees. Electronic submission is strongly

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encouraged; however, paper-based submissions will continue to be accepted for those who choose not to submit electronically.