January 14, 2013

United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 13-02

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

FROM: Richard E. Hill, Jr. */s/ Richard E. Hill, Jr.*
Director
Center for Veterinary Biologics

SUBJECT: Quarterly Acknowledgement Summaries for Selected Submissions

I. PURPOSE

The Center for Veterinary Biologics (CVB) is currently implementing methods to increase efficiency. This Notice announces that the Policy, Evaluation, and Licensing (PEL) unit of the CVB will begin distributing quarterly acknowledgement summaries, in lieu of individual regulatory response letters, for routine or minor submissions to PEL that are not considered time sensitive and to which the CVB does not take exception.

II. BACKGROUND

The PEL unit writes numerous regulatory response letters simply to acknowledge receipt of acceptable routine or minor submissions that do not require a time-sensitive reply. Each of these letters takes time to write and must undergo a quality assurance process before being mailed. Substantial efficiency is gained by combining acknowledgements in a summary format that can be generated as a report from the CVB's submission tracking system.

III. POLICY

Instead of sending individual acknowledgement letters for each submission received by PEL, licensees, permittees, and applicants will receive quarterly acknowledgement summaries in tabular format for certain eligible submissions. An example summary is appended to this Notice. Every submission to the PEL will be acknowledged either by individual letter or quarterly summary.

Eligibility of individual submissions for inclusion in the quarterly summary will be made on a case-by-case basis, at the discretion of the PEL. Eligible submissions may include, but are not limited to:

- Preliminary proof-of-concept studies filed solely for information (unless feedback is specifically requested).
- Simple non-pivotal study summaries submitted as follow-up to authorizations under 9CFR 103.3.
- Label inactivation requests.
- License termination requests (after licensee surrenders licenses to the CVB).
- Return of superseded licenses (e.g., after reissue). Notification of intent to discontinue product development (converting license applications to inactive status).
- Removal of personnel from list of USDA liaisons and assistant liaisons.
- Inspection-Compliance (IC) submissions submitted to PEL staff by mistake (e.g., facility documents). IC staff will respond in real time, but PEL acknowledgement of transfer to IC will be on summary.
- Regulatory review priority lists.
- Adverse event monitoring summaries, when required on an established periodic basis for license maintenance, and provided the CVB has no particular comments to communicate.
- Routine updates to filed documents for unlicensed products exported under the Food and Drug Administration's Export Reform and Enhancement Act of 1996.
- Lists of critical study dates.

Additional submission scenarios may be identified for inclusion in the summary. An updated list of eligible submissions will be maintained at http://www.aphis.usda.gov/animal_health/vet_biologics/vb_pelmanual_ToC.shtml.

If a submission involves a request for PEL action (e.g., label inactivations, forwarding items to Inspection-Compliance), action will continue to be initiated upon receipt, but confirmation of the completed action will be communicated to the submitter via the quarterly summary.

The summaries will be generated at the end of each calendar year quarter (March 31, June 30, September 30, December 31) and distributed to the primary USDA liaison for the establishment within two weeks afterward. Unless otherwise requested by the submitter, summaries in PDF format will be distributed by electronic mail.

The quarterly summary is intended only for simple acknowledgement responses that are not time sensitive and will not impact the progress of product development plans. If, however, a submitter wishes to verify the disposition of a particular submission prior to the end of the quarter, an interim summary may be requested at any time. Address requests to your assigned licensing reviewer.

IV. IMPLEMENTATION/ APPLICABILITY

This new policy applies to any eligible PEL submissions reviewed on or after January 1, 2013. The first summary will be distributed for the quarter ending March 31, 2013.

EXAMPLE

Center for Veterinary Biologics
Submission Acknowledgement Summary for Establishment ABC
Covering Period January 1 – March 31, 2012

Mail ID	Product	Brief Description	Submission Date	Submission Type	Submission Subtype	CVB Action
103161	1000.00	Summary of preliminary efficacy study—equine influenza	01/18/2012	Report	Efficacy-proof of concept	Filed for information
103117	NA	Firm ABC's regulatory review priorities	01/13/2012	Correspondence	Administrative	Filed for information
104111	1999.AB, 4999.0A	Discontinuing development of these products	02/27/2012	Correspondence	Administrative	Converted product status to prelicense inactive and archived files.
105166	2999.99	No longer using labels 39482 and 39874	03/02/2012	Correspondence	Labeling	Labels moved to inactive status

Print date: 04/02/2012