



July 13, 2012

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 12-14

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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

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

SUBJECT: Revised Procedure for Depletion of Existing Inventories of Superseded Labels

I. PURPOSE

This Notice announces a revised Center for Veterinary Biologics (CVB) policy regarding the depletion of existing inventories of labels that have been replaced. The revised policy establishes a default period of one year to deplete inventories and improves processing efficiency of label submissions by the CVB.

II. BACKGROUND

In 2006, the CVB established a standard procedure for licensees and permittees to request permission to deplete the existing inventory of a superseded label before, or concurrently, using the one that replaced it. Under the previous procedure, the licensee or permittee specified a date by which the superseded label would no longer be used. The CVB authorized use via a comment on the APHIS Form 2015 (2015) that was returned in response to the label submission.

III. ACTION

Submit replacement labels under cover of a 2015. Specify on the mounting sheet and the 2015 the CVB-issued identification numbers of the labels being replaced. If applicable, use Block 16 (Remarks) of the 2015 to request permission to use the remaining inventories of the superseded labels.

The default period to use superseded labels is one year unless longer dating is specifically requested in Block 16. Expiration dates are standardized to the last day of the twelfth month after the date in Block 21 (Date Returned). Either the new or superseded labeling may be affixed to, or packaged with, the product before, or on, the expiration date.

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Superseded labels are removed from the active label list and archived by the CVB after the expiration date. Superseded labels should not be used after this date.

The CVB will no longer add an acceptance comment to Block 19 (Exceptions) of APHIS Form 2015 if the request for continued use is acceptable without modification. If the request is denied, or is acceptable with modification, specific comments will be added to Block 19. An authorized CVB signature in Block 20 of APHIS Form 2015 indicates CVB concurrence with stated requests, as modified by any comments that may appear in Block 19.

IV. IMPLEMENTATION/ APPLICABILITY

This policy applies to all labels processed by the CVB after the date of this Notice.

ARCHIVED