



April 20, 2006

United States
Department of
Agriculture

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-12

Animal and Plant
Health Inspection
Service

Subject: Authorization to Use Remaining Inventories of Replaced Labels

Veterinary Services

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

Center for Veterinary
Biologics

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I. PURPOSE

This notice serves to request that all licensees, permittees, and applicants utilize a standard procedure when submitting labels intended to replace existing labels once the current inventories of the existing label have been depleted.

II. BACKGROUND

When a submitted label is intended to replace an existing label(s), the identity of the label(s) to be replaced should be included on the label mounting sheet (9 CFR 112.5(d)(4)) and in Section C of Blocks 8-11 on APHIS Form 2015. It has come to our attention, however, that when firms wish to continue using the old label until current inventories are depleted, some firms will indicate that the new label is "in addition to" the old label instead of replacing it. When this occurs, the old label remains in the active files of the Center for Veterinary Biologics (CVB) indefinitely, as it is not flagged for archival. The following policy ensures that such labels are archived at an appropriate time, enhancing the ability of the CVB to maintain accurate current label lists.

III. ACTION

A. When submitting labels that will replace an existing label(s), specify on the mounting sheet and on APHIS Form 2015 that the superseded label(s) is being replaced. If applicable, include a statement in Block 16 of APHIS Form 2015 requesting permission to use the remaining inventories of the superseded label(s). Propose an expiration date for the superseded labels, after which they may be removed from the current label list and archived.

When the CVB processes the submitted labels, the reviewer will confirm in Block 19 (Exceptions) of APHIS Form 2015 that the request for continued use has been granted and will specify an actual expiration date. Prior to the expiration date, both the new and superseded labels may be used.

B. The CVB is currently reviewing the current label lists for each firm. If your firm has been identifying superseded labels as “in addition to” their replacements instead of using the procedure identified in Section III.A of this notice, and if you have not submitted a current label list to the CVB since January 1, 2005, please submit a current label list by August 15, 2006. Identify on the list which labels will need to be archived as soon as their current inventories are depleted, and propose an expiration date for these labels.

/s/ Richard E. Hill

Richard E. Hill, Jr.
Director
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ARCHIVED