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United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Washington, DC 20250

VETERINARY SERVICES MEMORANDUM NO. 800.208

TO: VS Management Team (VSMT)
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

FROM: John R. Clifford */s/ John R. Clifford*
Deputy Administrator
Veterinary Services

SUBJECT: Special Labels for Product for Export

I. PURPOSE

This document provides guidance to veterinary biologics licensees, permittees, and applicants concerning the approval of special labels for use on USDA-licensed veterinary biological product for export.

II. BACKGROUND

The labeling requirements for veterinary biologics licensed by USDA are set forth in title 9, *Code of Federal Regulations* (9 CFR), part 112. Each biological product prepared at a licensed establishment must be packaged and labeled as prescribed therein.

However, because of differences in Animal and Plant Health Inspection Service (APHIS) veterinary biologics licensing and labeling requirements versus those same requirements that may be acceptable to regulatory authorities in foreign countries, certain labeling requirements applicable to product intended for domestic distribution may not reflect the information required to be included in labeling for product produced in the United States but exported to a foreign country. In such cases, APHIS may approve special labels for use on biological products to be exported to such a country in accordance with 9 CFR 112.2(e). This document provides guidance for requesting approval of special labels for product for export.

III. GUIDELINES

A. General. Firms requesting approval of special labels for products for export to a foreign country must submit a copy of the proposed special label along with documentation demonstrating the approval of the importing country. This documentation can take a number of different forms, as a country's typical method of acknowledging approval may vary from country to country. Documentation requirements may be dependent on the importing country's ability

to adequately regulate veterinary biologics. Supporting documentation should not be from nongovernmental bodies or persons and should be in English, or the firm must provide an English translation.

B. Restrictions. Special labels may be approved subject to the following restrictions:

1. Special labels may be approved for products produced in a USDA-licensed establishment under a U.S. Veterinary Biological Product License in accordance with an Outline of Production on file with APHIS. For example, differences in expiration dating approved by a foreign regulatory authority with a demonstrated ability to regulate veterinary biologics are permissible. Where the specifications for the product as approved by such a foreign authority differ from USDA release criteria (e.g., potency release values), the manufacturer may utilize export pathways under either the FDA Export Reform and Enhancement Act of 1996 (See V.S. Memorandum 800.94) or seek licensure as a "For Export Only" product under a new USDA Product Code, based on the previously licensed product.

2. Labeling information included in the filed Outline of Production will reflect claims and other information that have been reviewed and approved by the CVB. This does not prevent special labels where both the content and format may differ from U.S. standards from being approved, but rather minimizes outline changes that would otherwise be required each time new foreign labeling requirements are encountered.

3. If the product has labeling that is approved under the "special label" provisions of the regulations that are contrary to what's allowed domestically, and makes claims for which supporting data has not been approved by USDA, those products will not carry a U.S. Establishment number. Products that are labeled with special labels should be shipped in shipping containers that are clearly marked, "For Export Only" or equivalent statement and shall not be diverted for domestic use. Enclosures, if needed, may be included with the product or may be added at the point of final destination in accordance with the requirements of the importing country. Products that enter the export market will have a U.S. Establishment number on their labeling if they meet all U.S. regulatory standards for use, claims, etc.

4. The CVB will conduct serial release testing of product with approved special labels as specified in the APHIS filed Outline of Production for product for domestic distribution. At the time of release, products must demonstrate that they meet U.S. testing requirements. Requests to conduct alternative potency testing or other special test procedures to satisfy foreign regulatory requirements will not be performed, and such tests may not be specified in the Outline of Production. The CVB also will not review or certify the results of alternative potency or other special test procedures to satisfy foreign requirements conducted by the firm.

5. In cases where claims are made on special labels that are outside of the USDA's regulatory jurisdiction, it is the responsibility of the manufacturer to ensure that they are in compliance with any applicable regulations.

6. Special labels may display proof of registration information required by the importing country (registration number, address of importer, etc.), provided that such information is not used in a manner which could falsely indicate that the distributor is the manufacturer of the product. The use of affiliated corporate names and addresses is permissible.

7. Manufacturers that are found to have abused the use of special labels may have their requests for such exemptions cancelled or denied.

These special labeling provisions are not meant to be in lieu of methods or authorities that may have been utilized in the past to provide flexibility in export labeling. They are meant to be additional tools to meet those needs.