USDA
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. 22-08

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

**FROM:** Byron E. Rippke
Director

BYRON RIPPKE Digitally signed by BYRON RIPPKE
Date: 2022.08.19 12:07:51 -05'00'

**SUBJECT:** Review of Labels for Use in Countries that are Members or Observers of the Veterinary International Conference on Harmonization

## I. PURPOSE

The purpose of this Notice is to inform licensees and applicants that the Center for Veterinary Biologics (CVB) is exercising regulatory discretion and allowing United States Department of Agriculture (USDA) licensed manufacturers to bypass the normal label review for labeling used on products destined for Veterinary International Conference on Harmonization (VICH) member or observer countries. This policy will result in savings and efficiency for both CVB and the regulated industry without any expected untoward effects.

## II. BACKGROUND

The CVB currently reviews all labels used on USDA licensed veterinary biologics to ensure labels comply with the regulations and do not contain false or misleading information. The authority to conduct this regulatory oversight is outlined in title 9, *Code of Federal Regulations (CFR)*, part 112. Labels designed for veterinary biologics being exported to countries other than the United States are included in the review process. In response to input from veterinary biologics manufacturers, CVB reviewed its policy regarding international labels. CVB is aware that other countries' regulatory authorities require similar label reviews through interactions with those authorities. Since VICH member and observer countries conduct thorough product and label reviews prior to allowing U.S. manufactured products to be marketed in their countries, CVB is exercising regulatory discretion and allowing USDA licensed manufacturers to bypass the normal label review for labeling used on products destined for VICH member or observer countries.

## III. ACTION (or POLICY)

A. *Eligibility.* The countries for which label review is eligible to be discontinued include:

1. VICH Members: European Union (EU) and Japan.

2. European Economic Area (EEA) countries when included in EU registrations: Iceland, Liechtenstein, and Norway.

3. VICH Observers: Australia, New Zealand, and South Africa.

   Canada's regulators have requested not to be included in this proposal to maintain participation in the web-based product summary postings, see section D below.

4. The United Kingdom

5. Switzerland, when included in or recognizing an EU registration.

B. To request discontinuation of label review in eligible countries:

1. Submit a formal request to CVB to discontinue submissions of export-only labeling for the specific region (EU) and/or eligible countries (section A. above). Include affected product code numbers.

   a. Requests for countries other than those in the EU will only be granted as country-specific for all products manufactured by the firm for a given eligible country.

   b. The request is only relevant to export-only labeling for products that are not distributed to any additional countries.

2. Prior to making a request, a firm should consider aspects such as Certificates of Licensing and Inspection (CLI) or Export Certificates. No Export Certificates (APHIS Form 2017) will be issued for countries with a labeling submission exemption. If a firm requests a CLI for a country with a labeling submission exemption, the firm must include the following statement on the CLI:

   "ATTENTION: The Center for Veterinary Biologics has not reviewed the export labeling of this product. Label claims should be reviewed and approved by the importing country to ensure accuracy."

C. *CVB Approval*.

After reviewing the request, CVB will provide written authorization for the firm to discontinue submission of export-only labeling for the specific eligible countries deemed acceptable. CVB may request additional information. Firms must add a statement indicating the Mail Log number with the approved exemption and the applicable countries in Section VI.D of the Outline of Production prior to the approval taking regulatory effect. Alternatively, firms may create a Special Outline which includes this information and reference the Special Outline in Section VI.D of the Outline of Production. Include with this submission a cover letter which lists label numbers that will be inactivated. Once the Outline of Production is filed, firms will have a transition period of six months to use remaining stocks of previously

approved, printed labeling, but may not print additional quantities. At the end of the six-month period, previously approved labeling will be inactivated in CVB records.

D. *Labeling requirements*.

Eligible export-only labeling must not bear the firm's U.S. Veterinary Biologicals Establishment License Number or Product Code Number, and the exporter cannot otherwise represent the product labeling in any manner as having met the requirements for USDA approval. The labels must not reference the "productdata.aphis.usda.gov" website.

E. *Maintain Records*.

The firm is responsible for maintaining records of all such labeling for export, as per 9 CFR 116.8. Files and traceability are subject to USDA inspection.

F. *Compliance*.

If a firm is found noncompliant with the policy as stated by including non-eligible country labels, requesting and using certifications for countries with no label review, or keeping incomplete records, CVB approval for non-submission of export-only labeling could be revoked.

G. *Communication*.

CVB will inform the VICH participating countries of this change in policy.

IV. Implementation/Applicability

Updated policy in this Notice is effective immediately and will be incorporated into VS Memorandum 800.54 at its next revision.