



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 16-09

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

FROM: Byron Rippke
Director

SUBJECT: Submission of Foreign Language Labels

I. PURPOSE

Title 9, *Code of Federal Regulations* (9 CFR), parts 112.5 and 112.8 provide regulations for review and approval of labels. Title 21, United States Code Section 382 provides regulations regarding biologics exported under the Food and Drug Administration's Export Reform and Enhancement Act of 1996 (FDA-EREA). The purpose of this notice is to provide clarification regarding labels of biologics containing foreign language text.

II. BACKGROUND

Firms often submit labels that are used only for serials exported to foreign countries; therefore, foreign language labels are routinely submitted for approval. Special requirements for foreign language labels are outlined 9 CFR 112.5(e) and additional details regarding labels for export are included in 9 CFR 112.8. Labels for export may also undergo review and approval in the receiving country, which may have different labeling requirements, including allowing different labeling statements. In such cases, labels that do not meet the requirements of the 9 CFR may be approved for export purposes as either labels, or special labels for export, depending on the variance.

To expedite processing of foreign language labels, further clarification of the regulations regarding these labels and recommendations to facilitate review are provided herein.

III. POLICY

- A. When a foreign language label is submitted for review, an English translation must be accessible to ensure a thorough review of the label. The translation does not need to be literally word for word, but it must be accurate and complete, with no information inserted, deleted, or altered. A firm representative, taking legal responsibility for the statement, may submit this information.

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1. If there is an approved domestic label counterpart, 9 CFR 112.5(e)(1) states that the mounting sheet can merely cite the CVB-issued label number of the approved domestic label in lieu of an English translation. To expedite review, a legible copy of the approved label should be included in the submission. If this copy is not included in the submission, the CVB will return the label as sketch.
 2. As per 9 CFR 112.5(e)(2), if the foreign language label varies from approved information in the Outline of Production, an explanation for the differences shall be submitted. The explanation may be submitted by the firm and summarized in the comments section of the cover form accompanying the submission. If the APHIS regulations are not followed, and an English version is not submitted, the label will be returned as a sketch, with the comment that review could not be completed because an English version of the label was not submitted. This will allow the CVB to decrease expending resources on incomplete submissions that do not meet regulatory requirements.
 3. As per 9 CFR 112.5(e)(3), the foreign language portion of a bilingual label shall be a true translation of the English portion. A statement verifying that the foreign language portion of the bilingual label is a true translation of the English portion should be included on the mounting sheet. The CVB will process the label as a sketch if this verification is not supplied.
- B. To approve an export label containing variances to APHIS regulations, a copy of the foreign regulatory authorization from the receiving country must be submitted, as described in 9 CFR 112.2(e) and Veterinary Services Memorandum 800.208.
1. When a copy of the foreign regulatory approval of a label is submitted, ensure the authorization has not expired at the time of submission to the CVB. If the authorization is expired, the label will be returned as a sketch, with a request for a copy of a valid authorization that has not expired.
 2. If the foreign regulatory approval submitted includes a label that the foreign country has approved, make sure the label that the foreign country approved matches the label submitted for APHIS approval. If the foreign country approved label is not the same as the label submitted to CVB for approval, the label will be returned as a sketch with a comment to submit an authorization for the appropriate label.
- C. To file foreign language labels under the Food and Drug Administration Export Reform and Enhancement Act (FDA-EREA), a true translation of the labels must accompany the submission. The translation will provide adequate transparency to help expedite FDA-EREA submissions.

IV. IMPLEMENTATION/APPLICABILITY

This policy is effective immediately.