



May 10, 2011

United States
Department of
Agriculture

VETERINARY SERVICES MEMORANDUM NO. 800.94

Animal and Plant
Health Inspection
Service

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

Veterinary Services

Washington, DC
20250

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

SUBJECT: Food and Drug Administration's Export Reform and Enhancement
Act of 1996

I. PURPOSE

This memorandum provides guidance to licensees, permittees, and applicants concerning Animal and Plant Health Inspection Service (APHIS) implementation of the Food and Drug Administration's Export Reform and Enhancement Act (FDA-EREA) of 1996, Section 802 (21 U.S.C. 382), as it applies to veterinary biological products.

II. REPLACEMENT

This memorandum replaces Veterinary Services Memorandum No. 800.94, dated November 4, 1999.

III. BACKGROUND

Under the FDA-EREA, certain drugs, biologicals, animal drugs, and medical devices that are not approved for distribution and sale in the United States can be exported to another country if they meet the laws of the importing country and are approved for marketing in a country listed in the FDA-EREA. The FDA-EREA defines the term "drug" to include veterinary biological products, which require licensing by the Secretary of Agriculture under the Virus-Serum-Toxin Act (VSTA) of 1913.

Under the VSTA, veterinary biological products shipped in or from the United States must comply with U.S. Department of Agriculture (USDA) regulations and be prepared at a USDA-licensed establishment. However, the FDA-EREA supersedes these requirements and under certain conditions, permits certain veterinary biological products that are not USDA-licensed to be prepared for export. The following guidelines describe how APHIS will apply the provisions of the FDA-EREA to the production and export of veterinary biological products that are not approved (unlicensed) for distribution and sale in the United States.



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IV. POLICY

The FDA-EREA is composed of two sections (801 and 802). Section 801, concerning imports for exports, does not apply to veterinary biological products. Section 802, however, concerning exports of certain unapproved products, applies to veterinary biological products that require licensing under the VSTA. This includes products that meet the definition of “biological products” in title 9 of the *Code of Federal Regulations* (9 CFR), section 101.2.

- A. Provisions of the FDA-EREA – A summary of the provisions of Section 802 of the FDA-EREA that apply to veterinary biological products is below. This summary includes references to the applicable sections of the FDA-EREA, which is available on the Internet at:

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm125799.htm>

1. *Export to Any Country* – A person may export an unlicensed veterinary biological product to any country if the product complies with the laws of the import country and the exporter has a marketing authorization for the product from the appropriate authority in Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, the European Union, or a country in the European Economic Area. Reference: 802(b)(1)(A).
2. *Notification to Center for Veterinary Biologics–Policy, Evaluation, and Licensing (CVB–PEL)* – If a person produces the product in facilities that are not USDA licensed and export is to one of the countries specifically listed in 802(b)(1)(A), the person notifies CVB–PEL, identifying the unlicensed veterinary biological product being exported and providing his or her name and address. Reference: 802(g).
 - a. If the import country is not one of the countries listed in 802(b)(1)(A), notification to CVB–PEL must include the name of the country to which the person is exporting the veterinary biological product, the identity of the veterinary biological product, and documentation as appropriate according to Sections IV.A. 5 or 6 of this memorandum.
 - b. If a person plans to produce an unlicensed product in a USDA-licensed veterinary biologics establishment for export under the FDA-EREA, notification to CVB–PEL also includes a request for authorization to produce unlicensed product in a licensed production facility in accordance with Section IV.B of this memorandum.

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3. *Maintain Records* – Any exporter of a veterinary biological product must maintain records of all such products exported and the countries to which they were exported. Reference: 802(g).
4. *Prohibited From Export* – A person may not export an unlicensed veterinary biological product under the FDA–EREA if the product:
 - a. Does not conform with current good manufacturing practice (GMP) requirements or other international standards recognized by the Secretary of Agriculture in its manufacturing, processing, packaging, and holding. Reference: 802(f)(1).
 - b. Is otherwise adulterated as defined in section 501 of the Food Drug and Cosmetic Act (21 U.S.C. 381). Reference: 802(f)(2).
 - c. Does not fulfill the requirements of Section 801(e)(1)(A) through (D) of the FDA–EREA, which states that a product is not deemed misbranded if the product:
 - (1) Meets the specifications of the foreign purchaser
 - (2) Is not in conflict with the laws of the country to which it is intended for export
 - (3) Is labeled on the outside of the shipping package that it is intended for export
 - (4) Is not sold or offered for sale in domestic commerceReference: 802(f)(3).
 - d. Presents an imminent hazard to the health and safety of the United States. Reference: 802(f)(4)(A).
 - e. Presents an imminent hazard to the public health of the country to which the product would be exported. Reference: 802(f)(4)(B).
 - f. Is not labeled in accordance with the requirements and conditions for use in both the country that has granted the marketing authorization for the product and the country to which the product would be exported. Reference: 802(f)(5)(A).
 - g. Is not labeled in the language and units of measurement of the country to

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which the product would be exported or in the language designated by such country. Reference: 802(f)(5)(B).

- h. Is not promoted in accordance with the labeling requirements set forth in 802(f)(5). Reference: 802(f)(6).
5. *Additions to the List of Approved Countries* – Countries can be added to the list of countries in 802(b)(1)(B).
- a. The appropriate country official, manufacturer, or exporter may request the Secretary of Agriculture to take action under 802(b)(1)(B) by submitting documentation to CVB–PEL in support of designation.
 - b. If a person other than the appropriate country official requests designation, that person’s request for designation must include a letter from the country official indicating the desire to be designated. Reference: 802(b)(1)(C).
 - c. The Secretary of Agriculture may designate an additional country to be included in the list of countries in 802(b)(1)(A) if the country has:
 - (1) Statutory authority for experts to review the safety and effectiveness of veterinary biological products based upon the evaluation of adequate and well-controlled investigations and only approves the marketing of products that have been determined to be safe and effective. Reference: 802(b)(1)(B)(i).
 - (2) Statutory requirements that ensure the methods, facilities, and controls used for the manufacture, processing, and packing of veterinary biological products are adequate to preserve their identity, quality, purity, and strength. Reference: 802(b)(1)(B)(ii).
 - (3) Statutory requirements for the reporting of adverse reactions related to the use of veterinary biological products and for procedures that it follows to withdraw approval of unsafe or ineffective products. Reference: 802(b)(1)(B)(iii).
 - (4) Statutory requirements that labeling and promotion of veterinary biological products are in accordance with the approval of the product. Reference: 802(b)(1)(B)(iv).
 - (5) A valid marketing authorization system that is equivalent to the systems in the countries described in 802(b)(1)(A). Reference: 802(b)(1)(B)(v).

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6. *Export to Countries Not Listed in the FDA-EREA* – Persons may export unlicensed veterinary biological products to a country that is not listed in 802(b)(1)(A) if:
 - a. The product complies with the laws of the import country and has a valid marketing authorization by the responsible authority in that country. Reference: 802(b)(2)(A).
 - b. The Secretary of Agriculture determines (based on documentation submitted to CVB-PEL) that the requirements below are met in that country. Reference: 802(b)(2)(B).
 - (1) The importing country has statutory authority for experts to review the safety and effectiveness of veterinary biological products based upon the evaluation of adequate and well-controlled investigations and only approves the marketing of products that have been determined to be safe and effective. Reference: 802(b)(2)(B)(i).
 - (2) The importing country has statutory requirements that ensure the methods, facilities, and controls used for the manufacture, processing, and packing of veterinary biological products are adequate to preserve their identity, quality, purity, and strength. Reference: 802(b)(2)(B)(ii).
 - (3) The importing country has statutory requirements for the reporting of adverse reactions related to the use of veterinary biological products and for procedures that it follows to withdraw approval of unsafe or ineffective products. Reference: 802(b)(2)(B)(iii).
 - (4) The importing country has statutory requirements that labeling and promotion of veterinary biological products are in accordance with the approval of the product. Reference: 802(b)(2)(B)(iv).
7. *Products Not Meeting the Provisions of the FDA-EREA* – A veterinary biological product described in 802(a) that would not meet the conditions for approval under the FDA-EREA or conditions for approval of a country described in 802(b)(1)(A) or 802(b)(2) may be considered for export if the exporter petitions APHIS. APHIS must take action within 60 days of receipt of a petition sent to CVB-PEL containing the following:
 - a. Certification by the person exporting the product that the veterinary biological product would not meet the conditions for approval of a country described in 802(b)(1)(A). Reference: 802(b)(3)(B).

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- b. Credible evidence that the veterinary biological product would be safe and effective under the conditions of use in the country to which it is being exported. Reference: 802(b)(3)(A).
 - c. A request for approval of the export of the product from the appropriate animal health authority in the importing country certifying that it is understood that APHIS has not approved the veterinary biological product for export under the FDA-EREA and concurring that the scientific evidence that the product would be reasonably safe and effective is credible. Reference: 802(b)(3)(B).
8. *Export of Experimental Products* – A person may export an experimental product (produced in a licensed establishment according to 9 CFR 103.1 or in an unlicensed establishment that conforms to GMP or other recognized international standard) to a country listed in 802(b)(1)(A) in accordance with the laws of that country. Reference: 802(c).
9. *Export in Anticipation of Marketing Authorization* – A person may export a product intended for formulation, filling, packaging, labeling, or further processing in anticipation of marketing authorization in any country listed in 802(b)(1)(A) in accordance with the laws of that country. Reference: 802(d).
10. *Products for Tropical Diseases or Diseases Not of Significant Prevalence in the United States* – Veterinary biological products for tropical diseases or other diseases not of significant prevalence in the United States that do not otherwise qualify for export under the FDA-EREA may also be permitted to be exported under certain conditions, if production of the product in the United States does not endanger the livestock and poultry of the United States. Reference: 802(e).
- B. *Production of Unlicensed Veterinary Biological Products in USDA-Licensed Veterinary Biologics Establishments for Export Under the FDA-EREA* – The regulations in 9 CFR 114.2 prohibit the production of unlicensed veterinary biological products in USDA licensed veterinary biologics establishments except for experimental products authorized according to 9 CFR 103.1. Regulations in 9 CFR 114.2 prohibit production of unlicensed products in licensed production facilities unless authorized by CVB-PEL in accordance with 9 CFR 114.1. CVB-PEL may authorize an establishment to produce an unlicensed product in licensed production facilities if such production does not result in a risk of contamination of licensed products or a risk to the health of U.S. livestock or poultry.

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1. *Authorization to Produce Unlicensed Products* – CVB–PEL may authorize the production of unlicensed products in USDA-licensed establishments for export under the FDA–EREA if the establishment:
 - a. Produces unlicensed products only for export under the FDA–EREA, the product’s labeling does not bear a U.S. Veterinary Biologics Establishment License Number, and the exporter does not otherwise represent the product in any manner as having met the requirements for licensure.
 - b. Prepares all products, whether licensed or unlicensed, in locations indicated in blueprints and legends filed in accordance with 9 CFR part 108. Center for Veterinary Biologics–Inspection and Compliance may inspect the production facilities before the entity prepares FDA–EREA products to ensure production of the unlicensed product(s) does not pose a risk of contamination to licensed products or a risk to the health of U.S. livestock or poultry.
 - c. Prepares an Outline of Production in accordance with 9 CFR 114.9 for each unlicensed product. CVB will not stamp outlines as “filed,” but will review them to ensure they provide an adequate description of the method of production.
 - d. Appropriately tests the Master Seeds, Master Cell Stocks, and ingredients used in the production of the unlicensed product to ensure freedom from contamination with bacteria, fungi, mycoplasma, viruses, and other agents in accordance with 9 CFR part 113 or other acceptable national standards.
 - e. Fully characterizes and identifies Master Seeds and Master Cell Stocks used in the production of the unlicensed product as indicated in the Outline of Production.
 - f. Maintains records in accordance with 9 CFR 116.1 and 116.2 that include all products, whether licensed or unlicensed.
 - g. Submits reports prescribed in 9 CFR 116.5 for all products, whether licensed or unlicensed.

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2. Licensing of Products Produced Under the FDA-EREA

- a. If authorized by CVB-PEL, a person may produce unlicensed products for export under the FDA-EREA in the USDA-licensed establishment even though the person is not pursuing a U.S. Veterinary Biological Product License for the product.
- b. However, if the person applies for a license for the product and CVB-PEL issues the license, the person must stop producing and exporting the product under FDA-EREA on the date CVB-PEL issues the license. Also, the person must notify CVB-PEL in writing of his or her action of stopping within 10 business days of receiving the product license.