

FOOD AND DRUG ADMINISTRATION EXPORT REFORM AND ENHANCEMENT ACT OF 1996 (FDA- EREA)

(also known in CVB as DEREAA)

1. Overview

The FDA-EREA, signed by President Clinton in April, 1996, reformed the laws governing the export of unlicensed animal drugs and veterinary biologicals. The text of the regulations that apply to biologics are found in Title 21, United States Code, Section 382.

The Act allows the distribution and sale of unlicensed animal biologics to any country in the world as long as they are not licensed in the United States (i.e., not offered for sale in domestic commerce), the product is not banned, and marketing approval has been obtained from a foreign country with adequate regulatory oversight (as defined in The Act). The applicant is required to comply with the laws of the importing country, and shipping boxes must include labeling to show that they are intended for export. Compliance with 9CFR 112.8 (regulations for Export Only products) is also required.

Prior to the 1985 amendments to the Virus-Serum-Toxin Act, exports were not considered “interstate commerce” (thus not under our regulatory authority), but the USDA prohibited the manufacture of licensed and unlicensed products in the same establishment. USDA, both before and after 1985 (when exports were brought within the scope of interstate commerce), had generally been willing to grant export licenses for products that were approved in foreign countries. In addition, the 1986 passage of Section 802 of the Federal Food, Drug, and Cosmetic Act allowed export of new animal drugs and animal biologics to any of 21 specified countries, thus providing a second export option for biologicals.

The Act of 1996 not only expanded the list of countries to which exports could be made automatically (without prior approval by FDA or USDA), but it also provided a mechanism by which exports could be made to other countries.

2. References

[FDA Export Reform and Enhancement Act of 1996 \(Pub. L 101-124\)](#)

21 USC Sections 381 & 382

9 CFR Sections 108, 112.8, 113, 114.9, 116.1, 116.2, 116.5

[VS Memorandum 800.94](#)

3. Flow of information

We require companies that produce both products exported under FDA-EREA, and licensed products to file documents (described below) with the CVB-PEL to disclose their FDA-EREA activities.

Unlicensed establishments are not required to submit the same documentation to the CVB-PEL to produce and export product under the FDA-EREA; they are, however, required to submit “simple notification” of their export activities.

3.1 Applications and updates for FDA-EREA products are submitted by licensed firms to the CVB for review.

3.2 These documents are not reviewed by the Legal Instrument Examiner, but go directly to the reviewer. Outlines and labels are not submitted with APHIS Form 2015.

3.3 Reviewers respond to FDA-EREA submissions by letter or through the quarterly report generated in the ML.

4. Specific documentation supplied by the licensee

4.1 The firm must obtain marketing authorization from the appropriate government officials of a “qualifying” country. The authorization from the “qualifying” country (see Section 4.2.1) must be submitted for each product. Once the marketing authorization has been received, it is the firm’s responsibility to provide the CVB with simple notification specifying additional countries to which they are shipping product. Firms are encouraged to obtain marketing authorization for each country to which they are shipping; however, this is not a requirement under the Act, and such authorizations need not be filed with the CVB.

4.2 A copy of the Outline of Production for each product must be submitted in accordance with 9 CFR 114.9, without APHIS Form 2015. A copy of revisions, after they are approved by the competent foreign authority, must be filed with the CVB. It is not necessary to file a copy of the approval of revisions from the competent foreign authority at the CVB.

4.3 A copy of final container labels must be submitted, without APHIS Form 2015, if the labels will be applied to the products on licensed premises. Additional labels or replacements must be filed with the CVB after they are approved by the competent foreign authority. It is not necessary to file a copy of the approval from the competent foreign regulatory authority at the CVB.

4.4 Master Seeds, Master Cell Stocks must be fully characterized, tested, and identified as per 9 CFR 113; licensed firms must submit report indicating the characterization, purity and identity results of testing performed at their facility. The seed must be

maintained in the Research and Development area until the reviewer has authorized the transfer to production.

4.5 Facility documents (blueprints and legends) must be updated to identify facilities and equipment to be used for this unlicensed production. Precautions and procedures must be in place to prevent cross contamination in accordance with 9 CFR 108.

4.6 Any establishment exporting product under FDA-EREA must maintain/provide records and reports in conformance to 9 CFR 116.1, 9 CFR 116.2, and 116.5, just as with they do with licensed products.

5. Review guidelines

5.1 The reviewer, in conjunction with CVB-IC as necessary, must determine that production of the unlicensed product does not result in the risk of contamination of licensed products or a risk to the health of U.S. livestock or poultry. The reviewer must be assured that licensed establishments maintain high production standards in accordance with 9 CFR regulations, Veterinary Services Memoranda, and any CVB Notices.

5.2 The unlicensed product must be eligible for export under FDA-EREA.

5.2.1 Marketing approval must be obtained from a country with adequate regulatory oversight. These countries currently include: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and countries of the European Union (EU) and European Economic Area (EEA). Verify current member countries of EU and EEA using a trusted source. Once marketing approval from one of these countries is obtained, the product may be exported to any country, if the product complies with the laws of that country. It is the responsibility of the firm, not the CVB, to determine that the product is in compliance with the importing country's laws.

5.2.2 The product must be materially different than any product for which the company has a U.S. biological product license. A rule of thumb is that the product is considered materially different if the change is something for which we would require efficacy and/or safety data.

5.2.2.1 Examples of acceptable differences: a different Master Seed, different combination of antigens, different adjuvant

5.2.2.2 Examples of differences not sufficient to justify export by FDA-EREA: Addition (or deletion) of an inert ingredient, colorant, or preservative; different Section V test/different release values

5.2.2.3 Firms can export a product under the FDA-EREA while concurrently pursuing licensure of the product with the CVB. However, when a United States Veterinary Biologics Product License is issued, export of the product under the FDA-

EREA must be terminated, and the person must notify CVB-PEL in writing of the action of stopping manufacture and export of the product within 10 business days of receiving the product license.

5.2.2.4: A firm can export a DERE A product for further filling, packaging, and processing, in anticipation of marketing authorization. In this case, the firm sends the CVB a notification letter, which includes the approximate date that marketing authorization is anticipated.

5.3 Review the Outline to ensure that it contains an adequate description of the method of production. The Outline is not stamped or processed.

5.4 Ensure that any shipping labels state “For Export Only” and do not have the U.S. Veterinary Biologics Establishment License Number on them. Vial labels do not have to include the “For Export Only” statement, and should not have the U.S. Veterinary Biologics Establishment License Number on them. The labeling must conform to the laws of the recipient country. Foreign language labels should be submitted with an English translation, to ensure the reviewer can read the labels before labels are filed.

5.5 Review the reports for Master Seeds and Cells. If appropriate, authorize transfer of these materials to production areas. In general, the CVB does not do confirmatory testing on FDA-EREA seeds. Confirmatory testing may be performed, however, if the possibility exists that the seed or cell may later be used in licensed products.

5.6 Consult with CVB-IC to determine whether a special inspection is needed to ensure contamination risks to licensed products are within acceptable limits.

5.7 Ask the LSRTIS product codemaster to assign a product code to each FDA-EREA product. Code numbers for FDA-EREA products are assigned by the Code Master and contain the letter “U” in the 5th digit, e.g., Code 7060.U3.

5.8 Ask the LSRTIS establishment codemaster to assign an establishment code to any unlicensed manufacturer of FDA-EREA products who submits a simple notification to the CVB.

5.9 FDA-EREA products are entered into LSRTIS; FDA-EREA is a product license status.

5.10 FDA-EREA seeds and cells are not entered into LSRTIS unless confirmatory testing has been done and the seed/cell is eligible for use in licensed products.

6. CVB Responses to FDA-EREA submissions

Reviewers must acknowledge initial FDA-EREA submissions by letter.

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Routine updates to filed documents for unlicensed products exported under FDA-EREA are eligible for inclusion in the quarterly submission acknowledgement summary. These submissions may be logged out without response and will be included in the quarterly acknowledgement summary ([CVB Notice 13-02](#)).