# Guidance for Industry

## FDA Export Certificates

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**Food and Drug Administration**
**Center for Biologics Evaluation and Research (CBER)**
**Center for Drug Evaluation and Research (CDER)**
**Center for Devices and Radiological Health (CDRH)**
**Center for Veterinary Medicine (CVM)**
**Center for Food Safety and Applied Nutrition (CFSAN)**
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*Manufacturers Assistance, HFM-40*
*Center for Biologics Evaluation and Research*
*Food and Drug Administration*
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*(Phone: 301-827-4573),*
*Internet: http://www.fda.gov/cber/guidelines.htm*
*Mail: The Voice Information System at 800-835-4709 or 301-827-1800*
*or*
*Office of Training and Communication*
*Division of Communications Management*
*Drug Information Branch, HFD-210*
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*Food and Drug Administration*
*5600 Fishers Lane, Rockville, MD 20857*
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*Internet: http://www.fda.gov/cder/guidance/index.htm*
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*Communications Staff, HFV-12*
*Center for Veterinary Medicine (CVM)*
*7500 Standish Place*
*Rockville, MD 20855*
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## I. Introduction

This guidance document is intended to provide a general description of FDA Export Certificates to industry and foreign governments. Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply a certification relating to products subject to the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§321-397, and other statutes FDA administers.

## II. What are FDA Export Certificates?

Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply a "certificate" for products regulated by the Food and Drug Administration (FDA). A certificate is a document prepared by FDA containing information about a product's regulatory or marketing status.

## III. Why do foreign governments want FDA Export Certificates?

In many cases, foreign governments are seeking official assurance that products exported to their countries can be marketed in the United States or meet specific U.S. regulations, for example current Good Manufacturing Practice (cGMP) regulations. Review of an FDA Export Certificate may be a required part of the process to register or import a product into another country.

## IV. What Types of Export Certificates does FDA issue?

At the current time, FDA issues the following types of Export Certificates, although not all certificate types are issued for every FDA regulated product:

- The **"Certificate to Foreign Government"** is for the export of products that can be legally marketed in the United States.

- The **"Certificate of Exportability"** is for the export of products that cannot be legally marketed in the United States, but meet the requirements of sections 801(e) or 802 of the Act and may be legally exported.

- The **"Certificate of a Pharmaceutical Product"** conforms to the format established by the World Health Organization (WHO) and is intended for use by the importing country when considering whether to license the product in question for sale in that country.

- The **"Non-clinical Research Use Only Certificate"** is for the export of a product, material, or component, for non-clinical research use only, that is not intended for human use and which may be marketed in, and legally exported from the United States under the Act. These non-clinical research use only materials will be labeled in accordance with 21 CFR 809.10(c)(2) or 21 CFR 312.160, as appropriate, and exported as they are presently being sold or offered for sale in the United States.

- The **"Certificate of Free Sale" (Certificates for Export)** is for food and cosmetic products and dietary supplements that may be legally marketed in the United States.

- The **"Health Certificates for Food/Feed"** currently required primarily by the European Union (EU), are usually consignment-specific and often contain language pertaining to "compliance" of the particular product/consignment with foreign regulations. As a matter of policy, FDA does not issue export certificates that attest to compliance with another country's requirements. Rather, FDA may work with other governments to develop mutually acceptable language for the certificate, e.g., language recognizing "equivalence" rather than "compliance".
- The **"Specified Risk Materials of Bovine, Ovine and Caprine Origin Certificate"** is used for the export of gelatin that can be legally marketed in the United States. These certificates address concerns on raw material in regard to transmissible spongiform encephalopathies.

## V. Is FDA required to issue Export Certificates?

Section 801(e)(4) of the Act provides that FDA shall, upon request, issue certificates for human drugs and biologics, animal drugs, and devices that meet certain requirements of the Act. FDA is not required by law to issue certificates for foods, animal feeds, food and feed additives, cosmetics and dietary supplements that can be marketed, sold, and distributed in the United States, but the agency intends to continue to provide this service as resources permit.

## VI. Does FDA issue Export Certificates for unapproved products?

The 1996 FDA Export Reform amendments to the Act provided for FDA to issue certificates for exports of certain products even though the products are not allowed to be marketed in the United States. FDA issues Certificates of Exportability for biologics, animal drugs, and devices that may be exported under these provisions of the Act but may not otherwise be marketed, sold, offered for sale, or distributed in the United States. For human drug products, FDA issues a

Certificate of a Pharmaceutical Product containing a special notation that the product is unapproved instead of a Certificate of Exportability. FDA does not issue Certificates of Exportability for foods, dietary supplements, and cosmetics.

## VII. What does FDA mean, when it attests to compliance with current Good Manufacturing Practice (cGMP) regulations in an Export Certificate?

FDA performs periodic inspections for compliance with cGMP regulations for drugs, biologics, and medical devices of United States manufacturers that are registered and listed with us. FDA bases its attestation of compliance with cGMP regulations on the manufacturer's most recent FDA inspection or other available information. Generally, FDA cGMP regulations are intended to assure that the manufacturer can manufacture, process, package, and hold a product to assure that it meets the requirements of the Act as to safety, identity, strength, quality, and purity.

## VIII. When does FDA refuse to issue an Export Certificate?

FDA will not issue a Certificate to Foreign Government or a Certificate of a Pharmaceutical Product for products that do not meet the applicable requirements of the Act. Additionally, such certificates will not be issued if FDA has initiated an enforcement action (e.g., a seizure or an injunction). Other examples of circumstances for which certificates will not be issued include:

- Failure of the manufacturing facility(ies) to operate in compliance with the cGMP regulations (unless the particular exported product is not affected by the specific cGMP deficiencies);
- Manufacturing facility(ies) not registered or listed with FDA; and
- Manufacturing facility(ies) for which FDA has no inspectional information.

FDA will not issue Certificates of Exportability for products subject to section 802 of the Act if the manufacturing facility(ies) does not comply with cGMP regulations, unless the particular exported product is not affected by the specific cGMP deficiencies.

FDA also will not issue Certificates of Free Sale and Health Certificates for Food/Feed (which are used for food and cosmetics) when products are removed from sale or not eligible for legal sale in the United States (e.g., the product is under seizure or the firm is under injunction).

## IX. Does FDA charge a fee for Export Certificates?

For human drug, biologic, animal drug, and device export certificates issued under section 801(e)(4) of the Act, the agency may charge a fee of up to $175 if FDA issues a certificate within 20 days of receipt of a request for such a certificate. This fee may vary depending on the product type, but it will not exceed $175.

## X. What are the legal requirements for exporting unapproved products under sections 801(e) and 802 of the Act?

Sections 801(e) and 802 of the Act contains numerous legal requirements for exporting unapproved products and other products that do not comply with the relevant requirements of the Act for distribution and sale in the United States. For sections 801(e) and 802 of the Act refer to the following internet address: http://www.fda.gov/ora/import/impexp/ora_impexp_sec.html.

For further information on draft guidance announced for public comment and FDA regulations concerning the export of products that cannot be distributed or sold in the United States, refer to the following documents:

- February 1998, Draft FDA Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996. Refer to the following internet address: http://www.fda.gov/opacom/fedregister/frexport.html.
- December 19, 2001 (66 FR 65429), Final Rule: Exports: Notification and Recordkeeping Requirements to be codified at 21 CFR 1.101.

## XI. What are FDA's cGMP requirements for drugs, devices and biologics?

FDA's cGMP requirements for drugs are the requirements for the methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug (including a biologic) to assure that such drug meets the requirements of the Act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess (21 CFR Parts 210 and 211).

The cGMP requirements for devices are set forth in the quality system regulation (21 CFR Part 820). The requirements govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.

Biological products, depending on their intended use, must meet the cGMP requirements for either drugs or devices.

## XII. Where do I get more information?

For further information on Export Certification refer to the Compliance Policy Guide for FDA Staff, Sec. 110.100 Certification for Exports (CPG 7150.01) located on the internet at http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/cpg110-100.html.

For further information on Export Certification processing for specific product areas refer to the following websites:

Export Certification for Biological Products visit http://www.fda.gov/cber/exportcert.htm.

Export Certification for Medical Devices visit http://www.fda.gov/cdrh/devadvice/39.html.

Export Certification for Drug Products visit http://www.fda.gov/cder/guidance/cert98gu.pdf.

Export Certification for Veterinary Products visit
http://www.fda.gov/cvm/forms/exportcertificate.htm.

Export Certification for Foods and Cosmetics visit http://vm.cfsan.fda.gov/~lrd/certific.html.

European Union (EU) Export Certificates For Fishery and Aquaculture Products visit
http://www.cfsan.fda.gov/~dms/eucert.html.

Notice: establishment of lists of exporters of animal-derived commodities to the European Union visit http://vm.cfsan.fda.gov/~lrd/fr960404.html.

US FDA - EU Seafood Processor Export Certificate Lists visit
http://www.cfsan.fda.gov/~frf/sfeuexp.html.