FDA Export Certificates

Guidance for Industry [1]

Submit comments and suggestions regarding this document at anytime to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You should identify all comments with the title of this guidance document.

For questions on the content of this document, contact the following export representatives:

Biologics: Kimberly Cressotti 301-827-6201
Food (including Cosmetics and Dietary Supplements): View web site for appropriate Certificate POC:
http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm151486.htm (/Food/GuidanceRegulation/ImportsExports/Exporting/ExportCertificationContacts/ucm151486.htm)
Drugs: Betty McRoy 301-796-3218
Medical Devices: Leila Lawrence 240-276-0132
Veterinary Medicine and Animal Food: Vernon Toelle 240-402-5637

Additional copies of this guidance are available on the Internet or from:

Center for **Biologics** Evaluation and Research (CBER)
Office of Communication,Outreach and Development (OCOD) (HFM-40)
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448
Phone: 800-835-4709 or 301-827-1800
ocod@fda.hhs.gov (mailto:ocod@fda.hhs.gov)

or

Center for **Drug** Evaluation and Research (CDER)
Division of Drug Information - Office Communications
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: (301) 796-3400
druginfo@fda.hhs.gov (mailto:druginfo@fda.hhs.gov)

or

Center for **Devices** and **Radiological Health** (CDRH)
Division of Small Manufacturers, International, and Consumer Assistance (DSMICA)
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: (800) 638-2041
Fax: (301) 847-8149
Email: **dsmica@fda.hhs.gov (mailto:dsmica@fda.hhs.gov)**

or

Center for **Veterinary** Medicine (CVM)
Communications Staff, HFV-12
7519 Standish Place
Rockville, MD 20855
Phone: 240-402-7002

or

Center for **Food** Safety and Applied Nutrition (CFSAN)
5100 Paint Branch Parkway (HFS-550)
College Park, MD 20740
View web site for appropriate Certificate POC:
http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm151486.htm (/Food/GuidanceRegulation/ImportsExports/Exporting/ExportCertificationContacts/ucm151486.htm)

U.S. Department of Health and Human Services
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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Corrected April 2005
Corrected to update the Medical Devices contact phone number

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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. This guidance supersedes the document issued under this title in August 2002.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

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 of Free Sale" (Certificate of Export for Seafood)** is for food, including dietary supplements, and cosmetic products that may be legally marketed in the United States. (CFSAN)
- 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". (Office of Regulatory Affairs-Field Offices)
- 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. (CFSAN)
- 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. (CBER, CDER, and CVM)
- 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. (CBER and CDRH)

- The **"Certificate to Foreign Government"** is for the export of human drugs and biologics, animal drugs, and devices that can be legally marketed in the United States. (CBER, CDRH, and CVM)
- The **"Certificate of Exportability"** is for the export of human drugs and biologics, animal drugs, and devices 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. (CBER, CDRH, and CVM)

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 either meet the applicable requirements of the Act and may be legally marketed in the United States or may be legally exported under the Act although they may not be legally marketed in the United States. The Act does not require FDA to issue certificates for food, including animal feeds, food and feed additives, and dietary supplements, or cosmetics. However, since foreign governments may require certificates for these types of products, 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 inspections for compliance with cGMP regulations for drug, biologic, medical devices, human food and animal feed manufacturers that are registered and listed with the Agency. FDA bases its attestation of compliance with cGMP regulations on the manufacturer's most recent FDA inspection and 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
- When the product is not exported from the United States.

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 when products are under FDA regulatory action (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 complete request for such a certificate. This fee may vary depending on the product type, but it will not exceed $175. FDA has interpreted the 20-day period to mean 20 government working days.

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 contain 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 **FD&C Act Chapter VIII: Imports and Exports (/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVIIIImportsandExports/default.htm)**.

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 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=210)** and **211 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=211)**).

The cGMP requirements for devices are set forth in the quality system regulation (**21 CFR Part 820 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=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. Supplementary requirements for biological products are in 21 CFR Parts 600-680.

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) (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073830.htm)**.

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

- For **Biological Products** visit **Importing & Exporting (Biologics) (/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/BiologicsImportingExporting/default.htm)** to obtain a Certificate of Exportability, Certificate to Foreign Government, Certificate of a Pharmaceutical Product, or a Non-Clinical Research Use Only Certificate.
- For **Medical Devices** visit **Exporting Medical Devices (/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ExportingMedicalDevices/ucm050521.htm)** to obtain a Certificate of Exportability, Certificate to Foreign Government, or a Non-Clinical Research Use Only Certificate.
- For **Drug Products** visit **Certificate of a Pharmaceutical Product Application Instructions (/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM095808.pdf)**to obtain a **Certificate of a Pharmaceutical Product (/downloads/AboutFDA/ReportsManualsForms/Forms/UCM052388.pdf)**.
- For **Veterinary Products** visit **Exporting - Animal Feedand Drugs (/AnimalVeterinary/Products/ImportExports/ucm050074.htm)**to obtain a Certificate of Exportability, Certificate to Foreign Government, Certificate of Free Sale, or a Certificate of a Pharmaceutical Product.

- For **Cosmetics** visit**Cosmetic Exports (/Cosmetics/InternationalActivities/Exporters/default.htm)**to obtain a General Certificate or Product Specific Certificate.
- For **Foods** (including **Dietary Supplements**) visit "**Enter a Food Export Certificate Application Step-by-Step Instructions (/Food/GuidanceRegulation/ImportsExports/Exporting/ucm260332.htm)**" to obtain a Certificate of Free Sale or Certificate of Export.
  - European Union (EU) Export Certificates For Fishery and Aquaculture Products visit"**Export Certificates for Fishery/Aquaculture Products and Live/Raw Molluscan Shellfish (/Food/GuidanceRegulation/ImportsExports/Exporting/ucm120969.htm)**."
  - Notice: Establishment of lists of exporters of animal-derived commodities to the European Union visit ***Federal Register*** **Volume 75, Number 225,Nov. 23, 2010, pp. 71444-71446 (http://www.gpo.gov/fdsys/pkg/FR-2010-11-23/html/2010-29483.htm)**.
  - US FDA - EU Seafood Processor Export Certificate Lists visit **European Union (EU) Export Certificate List (http://www.accessdata.fda.gov/scripts/EUCert/EU-Cert-list.CFM)**.
- For further information on Information for FDA Regulated Industry visit **For Industry (/ForIndustry/default.htm)** on FDA's website.
- For further information on FDA Issued/Supported Export Certificates for Food visit http://www.cfsan.fda.gov/~lrd/certifi3.html.

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[1] This guidance has been prepared by the Office of International Programs in the Office of the Commissioner (OC) in cooperation with CBER, CDER, CDRH, CFSAN, CVM and ORA at the Food and Drug Administration.

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