

U.S. Food and Drug Administration
Office of International Programs



Guidance For Industry:
FDA Export Certificates

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Overview

- Introduction
- Defining FDA Export Certificates
- Types of Export Certificates FDA issues
- When FDA does not issue an Export Certificate
- Finding more information



Introduction

Guidance for Industry: FDA Export Certificates--

Provides a general description of FDA's Export Certificates to industry and foreign governments

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm>

Guidance for Industry: Exports Under the FDA Export Reform and Enhancement Act of 1996-- summarizes the requirements and procedures for exporting human drugs, animal drugs, biological products, devices, food, food additives, color additives, and dietary supplements that may not be sold or distributed in the United States.

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



What is FDA Export Certificate?

An export certificate is a document prepared by FDA containing information about a product's regulatory or marketing status.



Types of FDA Certificates

- The “Certificate of Free Sale” is for food (CFSAN)
- The "Certificate" for cosmetics (CFSAN)
- The EU "Health Certificates for Food " (ORA-Field Offices)



Types of FDA Certificates (2)

- The "Specified Risk Materials of Bovine, Ovine and Caprine Origin Certificate" (CFSAN)
- The "Certificate of a Pharmaceutical Product" (CBER, CDER, CVM)
- The "Non-clinical Research Use Only Certificate" (CBER, CDRH)



Types of FDA Certificates (3)

- The “Certificate of Foreign Government” (CDER, CBER, CDRH, CVM)
- The “Certificate of Exportability” (CDER, CBER, CDRH, CVM)



Are FDA Certificates Required?

Section 801(e)(4) of the Act

- Under the law the certificates are only required for human drugs and biologics, animal drugs, and devices that are legally marketed in the U.S.
- FDA is not required to issue certificates for food, including animal feeds, food and feed additives, and dietary supplements, or cosmetics, but we do.



Certificates for Unapproved Products

The 1996 Export Amendments, Section 801(e)(4)

- Certificates of Exportability for certain products even though not marketed in the U.S.
- Certificates of Exportability are issued for biologics, animal drugs, and devices under these provisions.
- Certificate of Pharmaceutical Products with special notation that the drug is unapproved is issued for human drugs.
- FDA does not issue Certificates of Exportability for foods, cosmetics and dietary supplements.



FDA's Attestation To GMPs

- FDA performs inspections for compliance with GMP regulations for drug, biologic, medical devices, human food and animal feed manufacturers.
- FDA bases its attestation of compliance with GMP regulations on the manufacturer's most recent FDA inspection and other available information.
- Generally, FDA GMP regulations assure that the manufacturer can manufacture, process, package, and hold a product to assure its safety, identity, strength, quality, and purity.



FDA's Refusal to issue Certificates

FDA will not issue CFG or CPP if the product does not meet the requirements of the Act or

- There is a seizure or an injunctions initiated.
- There are GMP deficiencies.
- The facility is not registered or the products is not listed.
- The product is not exported from the U.S.



FDA's Refusal to issue Certificates (2)

- FDA will not issue Certificates of Exportability for products subject to section 802 of the Act if the manufacturing facility does not comply with GMP regulations.
- FDA will not issue Certificates of Free Sale and Health Certificates for Food/Feed when products are under seizure or the firm is under injunction.
- FDA will not issues EU Export Certificates because this task was delegated to the Dept. of Commerce's National Oceanic & Atmospheric Administration Seafood Inspection Program (NOAA SIP)



Export Certification Compliance Guide

For information on Export Certificates 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/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073830.htm>



Biologics Export Certificates

For obtaining a “Certificate of Exportability”, “Certificate to Foreign Government”, “Certificate of a Pharmaceutical Product”, or a “Non-Clinical Research Use Only Certificate” for **Biological products** go to:

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/BiologicsImportingExporting/default.htm>



Medical Devices Export Certificates

For obtaining a “Certificate of Exportability”, “Certificate to Foreign Government”, or a “Non-Clinical Research Use Only Certificate” for **Medical Devices** go to:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ucm050521.htm>



Drug Product Export Certificates

For obtaining a “Certificate of Pharmaceutical Products” for **Drug Products** go to:

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM095808.pdf>

For Frequently Asked Questions about CDER issued Certificates go to:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/UCM318409.pdf>



Food Export Certificates

For obtaining an “Export Certificate” or a “Certificate of Free Sale” for **Food (including Dietary Supplements)** go to:

<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm2006911.htm>



Cosmetic Export Certificates

For obtaining a “General Certificate” or a “Product Specific Certificate” for **Cosmetic Products** go to:

<http://www.fda.gov/Cosmetics/InternationalActivities/ImportsExports/CosmeticExports/default.htm>



Fishery & Aquaculture Certificates

FDA no longer issues “EU Export Certificates” because this task was delegated to the Dept. of Commerce’s National Oceanic & Atmospheric Administration Seafood Inspection Program. For more information go to:

<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm120969.htm>

FDA maintains its EU Export Certificate List at:

<http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm126413.htm>



Export Certificate Application Forms

For obtaining an application form for Certificate to Foreign Government (3613), Certificate of Exportability(3613a), Certificate of a Pharmaceutical Product (3613b), Non-Clinical Research Use Only Certificate (3613c), Cosmetic & Colors Export Certificate (3613d), Food export Certificate (3613e), go to:

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>



THANK YOU!

Any Questions?