FDA Export Certification

Guidance for Industry

This version of the guidance replaces the one made available in February 2019. This revision of the guidance includes changes to reflect existing FDA policies concerning the issuance of export certifications, including with respect to the issuance of certain export certifications for food for humans or animals pursuant to section 801(e)(4) of the Federal Food, Drug, and Cosmetic Act.

Additional copies of the guidance are available from:

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., WO71, Room 3103
Silver Spring, MD 20993
Phone: 800-835-4709 or 240-402-8010
ocod@fda.hhs.gov
https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-informationbiologics/biologics-guidances

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 66, Rm. 5431
Silver Spring, MD 20993-0002
Email: CDRH-Guidance@fda.hhs.gov
https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products

Policy and Regulations Staff, HFV-6
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855

Phone: 240-402-7002

International Affairs Staff, HFS-550
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
Phone: 240-402-2380
https://www.fda.gov/FoodGuidances

For questions on the content of this document, please refer to the appropriate FDA Center based on product jurisdiction.

Biological Products for Human Use: The Center for Biologics Evaluation and Research (CBER) CBERExportCert@fda.hhs.gov, CBERBECATS@fda.hhs.gov or 240-402-9155

Drugs for Human Use: The Center for Drug Evaluation and Research (CDER) CDERExportCertificateProgram@fda.hhs.gov or 301-796-4950

Medical Devices: The Center for Devices and Radiological Health (CDRH) exportcert@cdrh.fda.gov or 301-796-7400 Press 3

Food for Human Consumption: The Center for Food Safety and Applied Nutrition (CFSAN) CFSANExportCertification@fda.hhs.gov or 240-402-2307

Cosmetics: The Center for Food Safety and Applied Nutrition (CFSAN) CAP-OCAC-CFSAN@fda.hhs.gov

Veterinary Medicine and Animal Food: The Center for Veterinary Medicine (CVM) CVMExportCertification@fda.hhs.gov or 240-402-2412

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 Food Safety and Applied Nutrition (CFSAN)
Center for Veterinary Medicine (CVM)
July 2004
Corrected: April 2005
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FDA Export Certification Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance document is intended to provide a general description of Food and Drug Administration (FDA or the Agency) export certification 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 FD&C Act) and other statutes FDA administers.

[1] This guidance has been prepared by CBER, CDER, CDRH, CFSAN, and CVM at FDA. You may submit comments on this guidance at any time. Submit comments to Docket No. FDA-2017-D-6821 (available at https://www.regulations.gov/docket?D=FDA-2017-D-6821). Submit written comments referencing Docket No. FDA-2017-D-6821 to Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. See the instructions in Docket No. FDA-2017-D-6821 for submitting comments on this and other Level 2 guidances.

This guidance supersedes the document issued under this title in July 2004, as corrected in April 2005 and February 2019.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, 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 IS FDA EXPORT CERTIFICATION?

FDA export certification provides information concerning a product and/or establishment's regulatory or marketing status, based on available information at the time FDA issues the certification (including, as appropriate, attestations provided by the person seeking the export certification). For some Centers, if a product has received approval or clearance from FDA, it will be indicated on the export certification and/or a copy of approved labeling will be appended, as appropriate. Upon the request of external stakeholders, FDA might issue an export certification to facilitate export of FDA-regulated products from the United States. The exporter is responsible for ensuring that the export of the product(s) to the intended destination(s) is in compliance with all other applicable U.S. statutes and regulations at the time of certification, such as provisions administered by the Department of Commerce's Bureau of Industry and Security and the Department of Treasury's Office of Foreign Assets Control. The fact that FDA has issued an export certification does not preclude FDA from taking appropriate regulatory action against an establishment or product covered by the certification. For example, FDA might take regulatory action against an establishment or product covered by export certification if additional information about the regulatory or marketing status of the product becomes available.

Submitting false or misleading information in a request for certification, substituting a product under a certification, counterfeiting or altering a certificate, or fraudulently using a certification may violate federal law and subject those responsible to civil and/or criminal liability.

III. WHY DO FOREIGN GOVERNMENTS WANT FDA EXPORT CERTIFICATION?

In many cases, foreign governments are seeking official assurance that products exported from the United States to their countries can be marketed in the United States or meet specific U.S. regulations, for example, as applicable, current good manufacturing practice (CGMP) regulations. A foreign government may also require export certification as part of the process to register or import a product into that country.

IV. WHAT TYPES OF EXPORT CERTIFICATES DOES FDA ISSUE?

FDA may provide export certification in various forms as we determine to be appropriate, and export certificates are one means by which we provide export certification. At present,

FDA issues several types of export certificates, although not all certificate types are issued for every FDA-regulated product. Most of these certificates are issued under section 801(e)(4) of the FD&C Act. Section 801(e)(4) of the FD&C Act provides that FDA shall, upon request, issue a written export certification for a human drug (including a biological product), animal drug, device, or food (including animal food and food for human consumption) that says the product either (1) meets the applicable requirements of the FD&C Act (see Sections V and VII of this guidance), or (2) meets the requirements of section 801(e)(1) or 802 of the FD&C Act[2] and may be legally exported from the United States (see Sections VI and VII of this guidance). As discussed in Section VIII of this guidance, export certification issued under section 801(e)(4) of the FD&C Act is subject to a fee.

The FD&C Act does not require FDA to issue export certification for cosmetics. However, because foreign governments may require certificates for cosmetic products, FDA intends to continue to provide this service as resources permit.

The following are examples of export certificates FDA issues:

- The "**Certificate of Free Sale**" as issued by CFSAN has historically been available for all foods for human consumption that are regulated by FDA and may be legally marketed in the United States or, if they cannot be legally marketed in the United States, meet the requirements of section 801(e) of the FD&C Act and may be legally exported. These certificates are not issued under section 801(e)(4) of the FD&C Act.[3] CFSAN intends to continue issuing Certificates of Free Sale for medical foods, foods for special dietary use, dietary ingredients, and dietary supplements. For other foods, CFSAN intends to phase out the use of Certificates of Free Sale.

- The **"Certificate of Free Sale"** as issued by CVM is for the export of animal food, animal drugs, or medicated animal feed that meet the applicable requirements of the FD&C Act for marketing in the United States. FDA issues these certificates under section 801(e)(4) of the FD&C Act.

- The "**Certificate for Cosmetics**" is issued by CFSAN for products that meet the definition of a cosmetic under section 201(i) of the FD&C Act. We do not issue these certificates for products marketed with drug claims, such as cleansers with acne treatment claims. These certificates are not issued under section 801(e)(4) of the FD&C Act.

- **Health Certificates** might be requested by other governments for human foods containing animal-derived ingredients; these requesters often seek FDA statements

[2] The text of sections 801(e) and 802 of the FD&C Act is available at https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act.

[3] FDA understands that some countries may have regulations that specifically require a document designated as a "Certificate of Free Sale" for human food product registration or acceptance of shipments. CFSAN will, if requested by industry, add a subtitle of "Certificate of Free Sale" to a "Certificate to a Foreign Government." When CFSAN does so, the Agency continues to consider the certificate to be a "Certificate to a Foreign Government" issued under section 801(e)(4) of the FD&C Act, and the certificate will include the same content as other "Certificates to a Foreign Government" and also be subject to the same fees as other "Certificates to a Foreign Government."

with respect to "compliance" of the particular product with foreign regulations. As a matter of policy, FDA generally does not issue certificates that attest to compliance with another country's requirements. Rather, FDA may work with other governments to develop mutually acceptable language for the health certificate. The CFSAN-issued health certificates for collagen or gelatin products exported to the European Union are examples of these types of certificates. FDA will consider requests for new health certificates on a case-by-case basis, as substantial time and resource commitments are required in negotiating the certificate language with a foreign government. Depending on the certificate language, such a certificate may or may not be issued under section 801(e)(4) of the FD&C Act. These certificates are issued by CFSAN.

- The **"Certificate of a Pharmaceutical Product"** is issued for human drugs (including biological products) and animal drugs. The certificate conforms to the format established by the World Health Organization (WHO) and is usually used by the importing country when considering whether to authorize the drug (including a biological product) in question for sale in that country. These certificates are issued under section 801(e)(4) of the FD&C Act by 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 FD&C Act. These non-clinical research use only products, materials, or components must be labeled as authorized in the United States in accordance with 21 CFR 312.160 or 809.10(c)(2). These certificates are issued under section 801(e)(4) of the FD&C Act by CBER and CDRH.

- The **"Certificate to Foreign Government"** is for the export of human food, human drugs (including biological products), animal drugs, animal food, medicated animal feed, and devices for humans or animals that meet the applicable requirements of the FD&C Act for marketing in the United States. These certificates are issued under section 801(e)(4) of the FD&C Act by CBER, CDRH, CFSAN, and CVM.

- The **"Certificate of Exportability"** is for the export of food, human drugs (including biological products), animal drugs, animal food, medicated animal feed, and devices for humans that cannot be legally marketed in the United States, but meet the requirements of section 801(e) or 802 of the FD&C Act and may be legally exported. These certificates are issued under section 801(e)(4) by CBER, CDRH, CFSAN, and CVM.

V. WHAT DOES FDA MEAN WHEN IT STATES IN AN EXPORT CERTIFICATION THAT AN ESTABLISHMENT IS IN COMPLIANCE WITH CURRENT GOOD MANUFACTURING PRACTICE (CGMP) REGULATIONS OR OTHER APPLICABLE REQUIREMENTS?

When FDA states in an export certification that an establishment is in compliance with CGMP regulations or other applicable requirements of the FD&C Act and FDA regulations, FDA bases this certification on the Agency's most recent inspection, if any,

of the relevant establishment(s) and other relevant information that is available to the Agency. There are some situations in which FDA cannot issue a certification stating that an establishment is in compliance with CGMP regulations or other applicable requirements. These include when an inspection is in progress or information from the inspection is under FDA review, in which case we might delay issuing a certification. Please refer to the appropriate FDA Center based on product jurisdiction for more information on applicable requirements for specific products.

VI. DOES FDA ISSUE EXPORT CERTIFICATION FOR PRODUCTS THAT MAY NOT BE LEGALLY MARKETED IN THE UNITED STATES?

Section 801(e)(4) of the FD&C Act provides for export certification of products that cannot be legally marketed in the United States, including unapproved products, if they meet the requirements of section 801(e)(1) or 802 of the FD&C Act and may be legally exported from the United States. Such certification includes Certificates of Exportability.

For unapproved new human drug products, CDER does not issue a Certificate of Exportability; instead, CDER issues a Certificate of a Pharmaceutical Product that includes a statement that the product is unapproved and meets the requirements of sections 801(e)(1) or 802 of the FD&C Act. For unapproved new animal drugs that meet the requirements of section 801(e)(1) of the FD&C Act, CVM may issue either a Certificate of Exportability or Certificate of Pharmaceutical Product.

Sections 801(e) and 802 of the FD&C Act contain numerous requirements for exporting unapproved products and other products that do not comply with the applicable requirements of the FD&C Act. For further information on these export mechanisms, refer to the Guidance for Industry: Exports Under the FDA Export Reform and Enhancement Act of 1996, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exports-under-fda-export-reform-and-enhancement-act-1996.

VII. WHAT CONDITIONS PREVENT ISSUANCE OF EXPORT CERTIFICATION?

When determining whether to issue export certification, FDA reviews records for relevant establishments and products and considers information and attestations provided by the person requesting the export certification. FDA does not intend to issue export certification if it determines that the establishments or products are not eligible for the requested certification or if the Agency does not have adequate information to make the required determination.

Some examples of circumstances that may prevent the issuance of export certification include:

- FDA has determined that the manufacturing establishment(s) and/or product(s) are not in compliance with applicable CGMP regulations or other applicable requirements.

- FDA has determined that the manufacturing establishment(s) and/or product(s) lack the required FDA registration and/or listing.

- FDA has initiated an enforcement action (e.g., a seizure or injunction) relevant to the establishment(s) and/or product(s).

When FDA does not issue an export certification, we generally will provide the reason(s) to the person requesting the export certification.[4]

VIII. DOES FDA CHARGE A FEE FOR EXPORT CERTIFICATION?

For export certifications for human food, human drugs (including biological products), animal food, animal drugs, medicated animal feed, and devices for humans or animals that FDA issues under section 801(e)(4) of the FD&C Act, we may charge a fee if we issue a certification within 20 days of receipt of a complete request for such a certification. This fee may vary depending on the product type, but it will not exceed the statutory maximum. FDA interprets the 20-day period to mean 20 government working days.

IX. WHERE DO I GET MORE INFORMATION?

For further information on export certification processing for specific product areas, refer to the following websites:

- **For Biological Products visit Exporting CBER-Regulated Products**
  https://www.fda.gov/vaccines-blood-biologics/compliance-actions-biologics/exporting-cber-regulated-products

- **For Drugs visit Human Drug Exports**
  https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-exports

- **For Medical Devices visit Exporting Medical Devices**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ImportingandExportingDevices/ExportingMedicalDevices/default.htm

- **For Veterinary Products visit Exporting - Animal Feed and Animal Drugs**
  http://www.fda.gov/AnimalVeterinary/Products/ImportExports/ucm050074.htm

- **For Cosmetics visit Cosmetic Exporters**
  https://www.fda.gov/cosmetics/cosmetics-international-activities/cosmetics-exporters

- **For Foods for Human Consumption visit Exporting Food Products from the**

[4] For information on FDA denial of a Certificate to Foreign Government for a device, see FDA's guidance for industry and FDA, "Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-request-review-fdas-decision-not-issue-certain-export-certificates-devices).

United States
https://www.fda.gov/food/food-imports-exports/exporting-food-products-united-states

FDA Export Certificate Web-based systems:

FDA offers web-based application systems for requesting certain export certificates. These systems are an alternative to paper submissions and may offer several benefits, including a reduction in certificate processing time, real-time validation, and status updates. Please click on the following link for available web-based export certification application systems: http://www.access.fda.gov.

FDA Export Certification forms:

FDA Export Certification forms (the Form Number 3613 series) can be found at https://www.fda.gov/about-fda/reports-manuals-forms/forms.

FDA References:

The Federal Food, Drug, and Cosmetic Act is available at https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act.

For further information on export mechanisms under sections 801(e) and 802 of the FD&C Act, refer to the Guidance for Industry – Exports Under the FDA Export Reform and Enhancement Act of 1996, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exports-under-fda-export-reform-and-enhancement-act-1996.