U.S. Food and Drug Administration ("FDA")

CONTACT INFORMATION

U.S. Food and Drug Administration
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The Food and Drug Administration’s mandate is to regulate safety and security standards for food, medications, medical devices, and certain cosmetics sold within the United States. FDA is an agency with the Cabinet-level Department of Health and Human Services.

The FDA regulates over $1 trillion U.S. dollars of consumer goods (25% of U.S. consumer expenditures) and monitors approximately a third of all U.S. imports\(^1\). The FDA’s role in recent years has expanded to working with other countries’ regulatory agencies to increase international cooperation on food and drug standards.

Import Program
http://www.fda.gov/ForIndustry/ImportProgram

The import program at the FDA helps ensure that imports into the United States meet U.S. standards. The FDA oversees all food, drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation. FDA’s import program complements the work of the Department of Agriculture, which is responsible for oversight of imported meat and poultry).

International Arrangements

The FDA and other agencies have negotiated confidentiality commitments of information sharing and memoranda of understanding with other governments to reduce regulatory duplicity and harmonize standards with other countries. These agreements make it easier for countries to trade food and drug products with each other while maintaining safety standards. In addition, the FDA works with global institutions such as the World Trade Organization to develop a set of international standards. These efforts are meant to pull resources from regulatory agencies to reduce compliance costs and minimize barriers for traders.

\(^1\) Food and Drug Administration, Retrieved 19 May 2014 at http://www.fda.gov/AboutFDA/WhatWeDo/History-Origin/ucm124403.htm
ADDITIONAL RESOURCES

For a full list of what the FDA regulates, go to [http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm](http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm)

Databases for Products [http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm](http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm)

This site links to major databases useful for those working with the FDA.

FDA Resources for Data Standards [http://www.fda.gov/ForIndustry/DataStandards/default.htm](http://www.fda.gov/ForIndustry/DataStandards/default.htm)

The spreadsheet provides a listing of supported and/or required standards, their uses, the date FDA will begin (or has begun) to support a particular standard, and the date support ends (or will end), the date the requirement to use a particular standard will begin (or has begun) and the date such requirement ends (or will end), as well as other pertinent information.

Outreach and Technical Assistance [http://www.fda.gov/Food/InternationalInteragencyCoordination/InternationalOutreachTechnicalAssistance/default.htm](http://www.fda.gov/Food/InternationalInteragencyCoordination/InternationalOutreachTechnicalAssistance/default.htm)

The FDA provides information on regulations and policies to foreign governments and businesses through the Center for Food Safety and Applied Nutrition. The center holds seminars, consults with foreign interests, and conducts training conferences to communicate safety standards and requirements for products in the United States. In addition, the center collaborates with academic institutions in research.

International Visitors Program [http://www.fda.gov/Food/InternationalInteragencyCoordination/InternationalVisitorsProgram/default.htm](http://www.fda.gov/Food/InternationalInteragencyCoordination/InternationalVisitorsProgram/default.htm)

The Center for Food Safety and Applied Nutrition heads the International Visitor’s Program, an initiative that welcomes foreign nationals from government, industry, academia, and the public sector for a period of time to learn about FDA policy and standards. The program is intended to promote global food safety and ensure that U.S. imports meet standards.

For Foreign Governments

International and Interagency Coordination [http://www.fda.gov/Food/InternationalInteragencyCoordination/default.htm](http://www.fda.gov/Food/InternationalInteragencyCoordination/default.htm)
Provides information on services offered by the FDA for foreign nationals interested in working in the US market.

*International Arrangements:* [http://www.fda.gov/InternationalPrograms/Agreements](http://www.fda.gov/InternationalPrograms/Agreements)

Lists the different memoranda of understanding and confidentiality agreements with other countries’ FDA equivalents.

**For Foreign Businesses**


Provides guidance and resources for industries needing to work with the FDA.

*Small Business Assistance:* [http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm](http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm)

Includes a Small Business Guide to the FDA and contact information for the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), which consults with smaller enterprises in standards and working with the FDA.

*Dispute Resolution:* [http://www.fda.gov/ForIndustry/DisputeResolution/default.htm](http://www.fda.gov/ForIndustry/DisputeResolution/default.htm)

An introduction to the FDA dispute resolution process for products.