

FDA IMPORTER/BROKER RESOURCES

The following links provide detailed information on specific commodities under FDA Review:

- <u>Importing Medical Devices into the U.S.</u>
- Status of Medical Device Establishment Registration & Device Listing
- Medical Device Classification Database and Obtain a Medical Device Product Code
- Medical Devices Who Must List, Register, and Pay the Fee
- National Drug Code (NDC) Database
- FDA Import Alerts and Sign-Up for Import Alert Email Update
- Import Filer Evaluation Outcomes
- Import Trade Auxiliary Communications Systems (ITACS)
- Import Trade Auxiliary Communications Systems (ITACS) Training Presentation
- Acidified & Low-Acid Canned Foods Guidance
- FDA ACS Affirmation of Compliance Codes (A of C)
- Food Safety Modernization Act Imports
- Importing Human Drugs and Biologics into the U.S.
- Register a Food Facility with FDA under CT Act
- Register a LACF of AF Food Facility

All analyses conducted by private laboratories and the reports submitted for those analyses are expected to conform to the guidance found in FDA's ORA Laboratory Manual, Volume III, Section 7, "Private Laboratory Guidance."

ASK FDA A QUESTION

- <u>Division of Enforcement and Import Operations Alerts and National Questions</u>
 - o Submit Change of Address, Import Alert Removal Petitions, ect.
- Food Prior Notice 866-521-2297 INTL: 571-468-1488 or Email
- Medical Devices <u>Division of Small Manufactures, International and Consumer Assistance</u> 800-638-2041 or Email
- Drugs and Biologics <u>Small Business Assistance: Import and Export of Human Drugs and Biologics</u> 888-463-6332 or Email
- ITACS Issues
- Low Acid Canned Food and Acidified Food Registration and Inquires
- FDA Food Facility Registration Questions