

Assistance With U.S. FDA Regulations

Food and Beverages



Medical Devices



Cosmetics



Drugs



Registrar Corp ★

FDA Food Facility Registration



The U.S. Food and Drug Administration

(FDA) requires both U.S. and foreign facilities to register with FDA if they manufacture, process, pack, or hold food, beverages, or dietary supplements for consumption in the United States. Registrar Corp provides comprehensive registration services. As a client, you receive:

- ✧ A U.S. FDA Registration Number and updates of your registration with FDA as required.
- ✧ A Certificate of Registration issued by Registrar Corp to assure your customers that you have a valid FDA registration, as well as to prevent the accidental loss of your critical information.

- ✧ Three free Prior Notices annually.
- ✧ Free FDA Compliance Monitoring for your company.

Non-U.S. Food Facilities must also designate a U.S. Agent for FDA communications. As your U.S. Agent, in addition to the above, Registrar Corp will:

- ✧ Facilitate interactions with FDA, including scheduling of FDA inspections.
- ✧ Provide guidance to help you prepare for a FDA inspection.
- ✧ Dispatch a Food Safety Specialist to your facility to help you prepare for a FDA inspection after you receive a Notice of Inspection date.

FDA Prior Notice

The Bioterrorism Act requires that a “Prior Notice” submission be filed with FDA before food, beverages or dietary supplements may enter the United States. This applies to shipments made by land, sea, air, mail, and express mail.

Registrar Corp provides a simplified fax or online Prior Notice filing service. Benefits include:

- ✧ Save and store commonly repeated data.
- ✧ Reduce Prior Notice filing time by 50%.
- ✧ Decrease potential filing errors.



Labeling & Ingredient Reviews

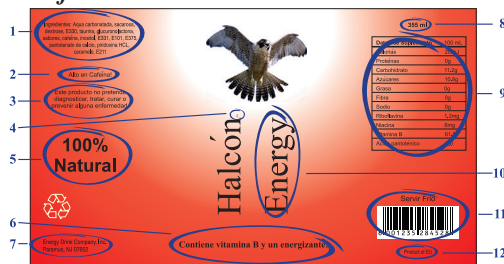
New FDA Labeling Rules issued in May 2016 require significant changes to food and supplement labeling, including updates to daily values, serving sizes, the Nutrition Facts chart, and more. The new rules became effective on July 26, 2016 and require most food manufacturers to comply by July 26, 2018. Manufacturers should update their labeling early to ensure a smooth transition and avoid being left with non-compliant inventory.

Registrar Corp helps companies comply with FDA's new labeling rules. Registrar Corp provides:

- ★ A detailed report (typically 30-40 pages) prepared by our team of Regulatory Specialists who review each element of your labeling, including the nutrition facts panel, ingredients, and product claims.
- ★ Once compliant, you will receive a print-ready graphic file of your revised label incorporating our recommended changes.
- ★ A generous revision policy providing additional reports and revisions for the same label within 90 days at no extra cost.

Example of a redesigned label provided by Registrar Corp as part of a review of your product labeling and ingredients.

Before:



After:



Import Alert Service

Companies shipping food to the United States often find their shipments detained by FDA pursuant to more than 250 different types of FDA Import Alerts. Registrar Corp will help:

- ★ Guide you through the process and properly draft your petition for removal from an Import Alert Red List or addition to a Green List.
- ★ Communicate with FDA for the release of shipments detained as a result of an Import Alert.
- ★ Follow up with FDA during the petition review process to address any questions or concerns from FDA.

FDA Canned Food (FCE/SID) Regulations

FDA requires companies that produce certain shelf-stable, hermetically-sealed acidified or low-acid foods to obtain a Food Canning Establishment (FCE) registration. In addition, manufacturers must submit documentation for each process used in the production of foods subject to these requirements. These “process filings” result in the creation of a Submission Identifier (SID) which serves as a unique product identifier. Registrar Corp’s FCE-SID Management Service helps companies avoid untimely delays and incomplete submissions by providing:

- ★ Expert guidance as to required elements, formats and particularities of FCE-SID submissions.
- ★ Certificates issued by Registrar Corp documenting your valid SID listings to assure your customers that your products have been properly filed with FDA.
- ★ Complimentary copy of Guidance Documents focusing on FDA’s low-acid canned food inspection procedures.

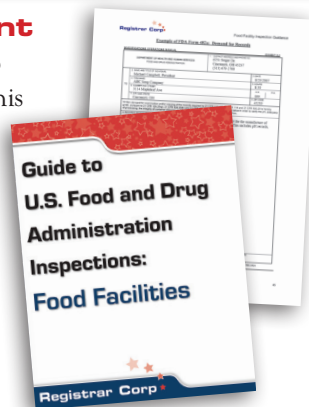


FDA Inspection Assistance

Registrar Corp’s Food Safety Department

will dispatch a Food Safety Specialist from our U.S. Headquarters to your facility to help you prepare in advance of a FDA inspection. This Pre-Inspection Assistance identifies potential problems with your facility, process, and procedures. Registrar Corp provides:

- ★ An on-site facility inspection, including a management debriefing, and a comprehensive written follow-up report outlining potential deficiencies.
- ★ Assistance in responding to FDA’s Notice of Inspection and to FDA’s 483 form observations following FDA’s actual inspection.
- ★ A free copy of our guide to U.S. FDA inspections.






FDA Compliance Monitor

Companies often don't realize they are not FDA compliant until their shipments are detained, leading to frustrating delays and unexpected expenses. Registrar Corp's FDA Compliance Monitor immediately alerts you to FDA compliance issues associated with your own company, as well as your suppliers, competitors, etc. Features include:

- ★ Ability to easily add and remove suppliers from your monitor lists.
- ★ E-mail updates anytime a change occurs in a company you are monitoring.
- ★ Printable report that easily documents the compliance history of your company and suppliers.

Import Alert(s)

-  **99-19 DWPE** Detention Without Physical Examination of Food Products due to The Presence of *Salmonella* for Capsicums (Cayenne Chili, Hot Peppers), Ground, Cracked (Spice) Description: Chili Powder Notes: 11/23/1998
-  **99-19 DWPE** Detention Without Physical Examination of Food Products due to The Presence of *Salmonella* for Capsicums (Cayenne Chili, Hot Peppers), Whole (Spice) Description: Chili Powder Notes: 11/23/98 Problems: *SALMONELLA*
-  **02-01 EXEMPT** This company is on the Green List and therefore exempt from DWPE for Rice, Basmati, Processed (Packaged) (FDA Product Code: 02D--07)

FDA Detention Assistance



For clients, Registrar Corp communicates with FDA compliance officers at the port to assist with FDA detentions. This free communication assistance can be critical in resolving detentions quickly and favorably.



Food Safety Plans & Programs

Registrar Corp's Food Safety Department can develop or review food safety plans and programs required by FDA, including those required under the Food Safety Modernization Act (FSMA). Have Registrar Corp assist with your:

- ★ Food Safety Plan
- ★ Foreign Supplier Verification Program
- ★ HACCP Plan
- ★ Food Defense Plan



Registrar Corp also offers multilingual assistance:

- * Medical Devices *
- * Cosmetics *
- * Drugs/Pharmaceuticals *
- * Radiation-Emitting Electronic Devices *

For additional information and a list of
worldwide offices please visit:
www.registrarcorp.com



Registrar Corp *

144 Research Drive * Hampton, Virginia 23666 USA
Phone: +1-757-224-0177 * Fax +1-757-224-0179
Email: info@registrarcorp.com



@RegistrarCorp



www.linkedin.com/company/registrar-corp



www.facebook.com/RegistrarCorp

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Registrar Corp is not affiliated with the FDA.***