## 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 an 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 483 form observations following FDA's actual inspection.



#### **FDA** Detentions



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 favorably and fast.



## **HACCP & Food Safety Plan Review**

Food Facilities often find that their HACCP Plans and documentation do not meet FDA requirements. Have Registrar Corp's Food Safety Department:

\* Create or review your existing HACCP Plan, including critical limits, monitoring procedures, verification procedures, flowcharts, and pertinent records.



## 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



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Registrar Corp assists businesses with FDA compliance. Registrar Corp is not affiliated with the FDA.

## **Assistance With** U.S. FDA Regulations

## Food and Beverages







Medical Devices





## Cosmetics





## Drugs





### 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. Additionally, foreign facilities must designate a U.S. Agent for FDA communications. Registrar Corp provides comprehensive registration services. As a client, you receive:

- \* A U.S. FDA Registration Number as well as renewal 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.

Non-U.S. Food Facilities are required to 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 an FDA inspection.
- ★ Dispatch a Food Safety Specialist to your facility to help you prepare for an FDA Inspection after you receive a Notice of Inspection date.





## Labeling & Ingredient Reviews

Registrar Corp helps companies comply with FDA's extensive labeling requirements by researching your labeling against thousands of pages within the Code of Federal Regulations as well as the Federal Register, EAFUS Database, GRAS Notices, Guidance Documents, Labeling Guides, and Warnine Letters issued by FDA. As a client, you'll receive:

- ★ 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.
- 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.

Import Alert Service







### FDA 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 providings.



- 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 Prior Notice**

**Companies shipping food** to the United States often find their shipments detained by FDA pursuant to more than 270 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 the Import Alert.
- ★ Follow up with FDA during the petition review process to address any questions or concerns from FDA.

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.

