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I 3 CONSULTING

United States Agent Services

Under the Code of Federal Regulation 807.40(b) the Food and Drug Administration requires a foreign establishment to designate a United States Agent to act as their official correspondent.

We have a proven track record assisting companies in registrations and Listings. As United States Agent for your company, we can ensure compliance with the new regulation, which became effective February 11, 2002.

Warning Letter Response

A Warning Letter has a profound impact on your business and business reputation. A Warning Letter is, in effect, just a continuation of the communication between the FDA and the company concerning your 483 response.

The Warning Letter will explain what has been accepted from your 483 response and what observation(s) were not appropriately addressed. Like the 483 response, a Warning Letter response must be comprehensive and address every aspect of the Quality System impacted by the correction.

483 Observations

A company's handling of responses to 483 Observations, Warning Letter and Recalls are critical to a company's survival in the present FDA regulation climate. A misstep at any point can result in product seizure, recalls, or company closure. A company's response must be timely, and comprehensive.

483 Responses

483 Observations after your factory audit by the FDA cannot be approached lightly. The comprehensiveness of your response is the only thing that is standing between your company and a Warning Letter.

Most responses must be returned to the FDA in 15 working days, so utmost haste when addressing 483 observations is critical.

Most companies respond to 483 in a conversational manner by explaining or justifying what happened. The FDA is looking for neither, but wants a response where appropriate actions are taken to remedy the observation. They want to review a response where a non conformance is opened, the observation is investigated to determine the root cause of the observation and if warranted what corrective and preventive actions will be taken to correct the observation.

If a CAPA is opened the respondent must detail each step to be taken to correct the observation based on the root cause analysis. Record each step to be taken in the corrective action and what steps will be taken to verify that the corrective action has been taken and no unintended consequences have occurred as a result of the corrective action. Additionally, the company should provide information on management follow-up to the observation.

Your response must be comprehensive and address every aspect of the Quality System impacted by the correction. I 3 Consulting is experienced in the responses and has been highly successful in preventing a Warning Letter being issued as a result of an inadequate response.

Systems cGMP Evaluation

Clients frequently turn-and return-to I 3 Consulting for world-class evaluations of their R&D systems, manufacturing systems and processes, and quality control/assurance systems. Just as important, they trust us to make powerful, effective recommendations for enhancing current systems and processes.

- Implementing quality by design for successful commercialization
- Analyzing and managing risk in the R&D and manufacturing environments
- In the realm of quality control and quality assurance systems, we're the "go-to" people when needs include:
- Assessing and managing risk vis-à-vis quality systems
- Evaluating and enhancing quality unit roles and responsibilities
- Assessing and improving facilities and equipment systems, materials systems, production systems, and laboratory controls systems

Due Diligence Audits

Through our extensive work in compliance and regulatory affairs and our consultants industry and FDA backgrounds I 3 Consulting is uniquely qualified to provide expert advice on compliance, scientific, and technical matters. Additionally, I 3 Consulting help clients through:

- Assessment of client-targeted organizations and facilities for compliance with current regulations
- Identification of deficiencies and gaps in compliance and provision of remediation plans
- Assessment of management controls
- Evaluation of executive and management personnel capabilities

Food, Feed & Dietary supplements

I 3 Consulting help clients to register facility of operation with United States Food and Drug Administration

All commercial acidified and low-acid canned food processors located in the United States and all processors in other countries who process acidified or low-acid canned food products for export to the United States must register with the FDA.

The U.S. Food and Drug Administration (FDA) established the Division of Food Contact Notification and Review within the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition's (CFSAN), to ensure components of food contact articles, including food packaging and processing equipment, are safe for their intended use.

Drugs and Active Pharmaceutical Ingredients

OTC Drug Establishment Registration with US FDA

Domestic and foreign establishments that manufacture, repack, or re-label OTC drug products or import or offer for import OTC drug products to the United States require FDA drug establishment registration, and renew the registration annually, FDA drug establishment registration information should be submitted electronically using SPL files with coded data fields. US FDA encourages electronic registration, even though you can submit registration in paper format if a waiver is granted. A Private Label Distributor (PLD) does not require US FDA drug registration. A contract sterilizer and Contract Testing Laboratory (dosage forms & active ingredient release) require US FDA registration but not listing. A foreign drug manufacturer also requires US FDA registration and listing, if drug from the manufacturer is marketing in the USA.

US FDA OTC Drug Labeling Requirements

US FDA is not pre-approving OTC Drug Labels marketed under OTC Monograph, but US FDA regulates all of the OTC Drug labeling like immediate container, outer package, package insert etc.. . The required information's include Drug Facts labeling and Principle Display Panel labeling. The regulations help to standardize the content and format of OTC Drug labeling. The registrant may upload the OTC drug labeling at the time of drug listing in SPL file format.

Medical Device

Establishment Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA.

510k Approval

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), PMA, PDP, HDE).

Cosmetics

Voluntary Cosmetic Registration program

The FD&C Act defines cosmetics as articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions. Included in this definition are products such as skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, shampoos, permanent waves, hair colors, toothpastes, deodorants, and any material intended for use as a component of a cosmetic product.

Cosmetics are not subject to FDA premarket approval or mandatory establishment registration or ingredient reporting. It is the firm's responsibility to assure that its cosmetic products and ingredients are safe and properly labeled, in full compliance with the law.

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