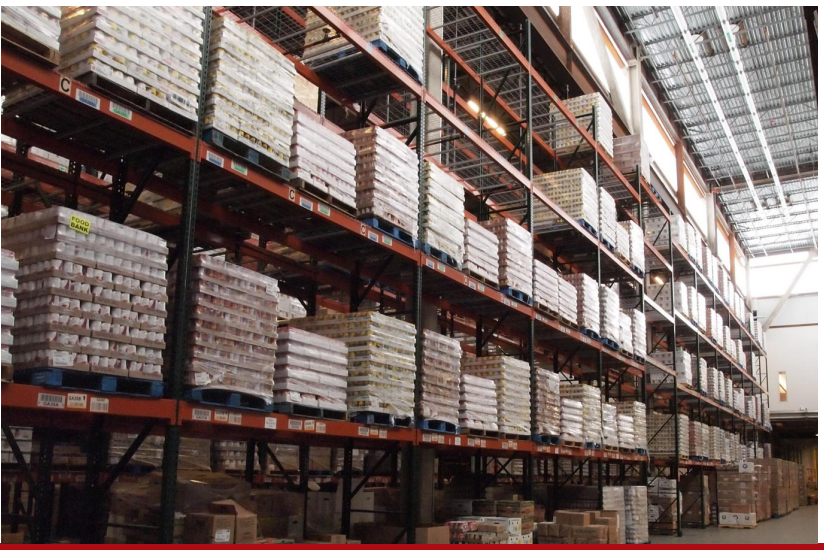
US Agent and Imports

Specializing in FDA Regulatory Matters

EAS CONSULTING GROUP

EAS Consulting Group, LLC is a leading provider of regulatory services to the pharmaceutical, medical device, food, dietary supplement, tobacco, and cosmetic industries. Originally founded in 1960, EAS has over 50 years of experience assisting clients in developing regulatory strategies, implementing quality systems, filing regulatory submissions, and ensuring compliance with all Food and Drug Administration (FDA) regulations. Employing a unique team of former FDA officials and industry experts, many with more than 30 years of experience, EAS has unparalleled expertise to assist clients with all of their consulting needs.

EAS Consulting Group provides registration and listing assistance as well as US Agent services to international clients in all FDA regulated areas. US Agents are required by FDA to act as an intermediary between foreign firms and FDA. By quickly responding to questions and concerns in a timely manner EAS helps clients get their compliant products to the US marketplace as quickly as possible.



- ✓ Establishment Registrations
- ✓ Drug Submissions (IND, DMF, ANDA, Amendments)
- ✓ Medical Device Applications and Correspondence (510(k), 513(g) PMA, IDEs, De Novo, Pre-Submission)
- ✓ Process Filing for Acidified and Low-Acid Canned Foods (LACF) & Establishment Registration
- ✓ Food Facility Registrations
- ✓ US Agent Services for Foreign Color Manufacturers Testing and Approval
- ✓ Preparation for FDA Inspections of Foreign Facilities
- ✓ Corrective Action Plans
- ✓ Assistance with FDA Import Requirements and Detained Product Clearance

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www.easconsultinggroup.com

EAS Consulting Group is readily available to assist our foreign clients in understanding and meeting the complex regulatory requirements of the FDA. Whether it is acting as an appointed US Agent, registering a facility, listing products, communication with the FDA or filing submission and amendments with the FDA EAS has the capability to meet your needs. Additionally, EAS can assist with import and detained product issues and procedures, assist with FD&C color certification requirements, perform GMP focused quality audits and conduct "mock-FDA" inspections. EAS has the expertise to provide a quick and accurate response to your compliance needs.

Drug Submissions:

EAS can assist with all pharmaceutical submissions to FDA and Health Canada when appointed as your US Agent. From INDs, DMFs, ANDAs and any subsequent amendments, your company can trust EAS to make recommendations and provide assistance with FDA submissions for your product(s). Our scientific experts in toxicology, radiology, chemistry and biology are authorities in government laws and regulations. EAS can lead your company through the process of obtaining necessary background data, filing the submissions, and following-up as needed during the submission process.

Medical Device Establishment Registration and Product Listing:

Most Medical Device firms who are required to register annually with the FDA are also required to list the devices that are made at their facilities and the activities that are performed on those devices. All Medical Devices are required to be listed with the FDA regardless of class or exemption status. If a device requires PMA or notification before being marketed in the U.S., then the FDA premarket submission number (510(k) and / or, PMA) should also be supplied. All foreign facilities are required to appoint a US Agent in their registration.

Medical Device Applications and Correspondence:

EAS can assist with all medical device submissions and correspondence [510(k), 513(g) PMA, IDEs, De Novo and Pre-Submission packets], assisting your company as your US Agent as well as support in developing the best strategy for filing approval.

Food Facility Registrations:

The Federal FD&C Act requires food and dietary supplement facilities which manufacture, process, package, or hold regulated product for consumption in the U.S. to register annually with the FDA. In addition, a Food Canning Establishment registration must be filed with the FDA before selling canned food products within or exporting canned foods into the U.S. This filing requirement is on top of the requirements placed on international facilities by the FDA's Bioterrorism Act Food Facility Registration requirement. Foreign facilities must have a US Agent to act as a communication between FDA and the foreign facility.

Establishment Registration & Process Filing for Acidified (AF) and Low-Acid Canned Foods (LACF):

A commercial processor, when first engaging in the manufacture, processing, or packing of acidified foods (AF) or low-acid canned Foods (LACF) shall register and file with FDA information including the name of the establishment, principal place of business, the location of each establishment in which that processing is carried on, the processing method, and a list of foods so processed in each establishment (21 CFR 108.25(c)(1) and 21 CFR 108.35(c)(1)). A commercial processor engaged in the processing of AF shall provide FDA with information, using Form FDA 2541e, on the scheduled processes for each acidified food in each container size (21 CFR 108.25(c)(2)). An analogous requirement for process filing, using either Form FDA 2541d, 2541f or Form FDA 2541g, applies to a commercial processor that manufactures, processes, or packs LACF (21 CFR 108.35(c)(2)).

US Agent Services for Foreign Color Manufacturers:

Color additives are subject to FDA approval, and in some cases each batch must be certified as safe by the FDA's Office of Food Additive Safety before they may be used in food, drugs, or cosmetics, or in medical devices that come in contact with the bodies of people or animals for a significant period of time. Petitioning companies must submit data demonstrating the safety and suitability as described in 21 CFR Part 71, prior to determination and subsequent listing in the CFR for use in foods, drugs, cosmetics, or certain medical devices. Foreign color manufacturers must also have a US Agent. EAS Consulting Group serves as the US Agent for foreign color manufacturers acting as intermediary between the foreign manufacturer and FDA.

Preparation for FDA Facility Inspections and Post-Inspection Response:

Once FDA files a Notice to Inspect, facilities will be given a specified amount of time to respond and begin preparations. EAS' team of former FDA investigators assists companies with "mock-FDA" inspections, to assist companies in determining any compliance deficiencies prior to FDA arrival as well as corrective action steps to be taken in an effort to bring the operation and its documentations into compliance. Should a facility receive a FDA-483, Inspectional Observations form or Warning Letter, there is a 15 day time frame in which to respond and EAS can help interpret the findings, assist in formulating an effective corrective action and with generating your response to the FDA.

Assistance with Detained Products

EAS Consulting Group assists companies with developing and planning product regulatory import strategies and time-lines. In addition EAS can assist companies whose products are under FDA detention. Whether the issue is lack of prior notice, inaccurate labeling and claims, product listing or filing issues, LACF registration problems or other issues, our experts in import issues will work with the authorities and your company to solve the issues surrounding your product's detention.

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