

FDA Submission Services

Specializing in FDA Regulatory Matters



EAS Consulting Group, LLC (EAS) is a leading provider of regulatory consulting services to the FDA regulated industries. The firm has over 50 years of experience assisting clients in developing regulatory strategies, implementing quality assurance programs, filing regulatory submissions and ensuring compliance with FDA regulations. Employing a unique team of former Food and Drug Administration (FDA) officials and industry experts, EAS offers unparalleled expertise, with most consultants having more than 30 years of FDA experience.



Various FDA submissions assistance is available from EAS to meet FDA requirements. This includes:

Foods/Dietary Supplements

- ✓ “Generally Recognized As Safe” (GRAS)
- ✓ Structure/Function Claim Notifications
- ✓ Food Facility Registrations
- ✓ New Dietary Ingredient Notices (NDI)
- ✓ Food and Color Additive Petitions
- ✓ Acidified and Low Acid Canned Food Registrations (AF and LACF)
- ✓ Infant formula Notifications

Pharmaceuticals

- ✓ Investigational New Drugs (IND)
- ✓ New Drug Applications (NDA)
- ✓ Abbreviated New Drug Applications (ANDA)
- ✓ Drug Master Files (DMF)
- ✓ Structured Product Labeling (SPL)
- ✓ Citizen Petitions (CP)

Medical Devices

- ✓ Investigational Devices (IDE)
- ✓ 510(k) Premarket Notifications
- ✓ Premarket Approval (PMA)
- ✓ Establishment Registrations and Product listings

Colors for Cosmetics

- ✓ Colors for FDA Certification

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EAS Consulting Group, LLC (EAS) can make recommendations and provide assistance with FDA submissions for your product(s). With scientific experts such as toxicology, radiology, chemistry and biology and authorities in government laws and regulations, EAS' consultants can lead your company through the process of obtaining necessary background data, filing the submissions, and following-up as needed during the submission process.

Foods:

GRAS, or "Generally Recognized as Safe":

"GRAS", or Generally Recognized As Safe submissions are required under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act). Any substance that is intentionally added to food is a food additive, and these are subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

Structure/Function Claims Notifications:

The FDA requires firms to notify FDA for structure function claims no later than 30 days after the first marketing of the product that they are making claims in accordance with 21 CFR 101.93.

Food Facility Registrations:

The Federal FD&C Act requires food facilities which manufacture, process, package, or hold food for consumption in the United States to register with the FDA. Foreign facilities must also have a U.S. agent to act as a communication between FDA and the foreign facility. Food facilities must renew these registrations every other year. FDA has the authority to suspend the registration of a food facility in certain circumstances.

New Dietary Ingredient (NDI) Notices:

A manufacturer or distributor of a NDI, or dietary supplement that contains the NDI, is required to submit a premarket notification to FDA at least 75 days before the product enters the market, unless the NDI and any other dietary ingredients in the dietary supplement "have been present in the food supply as an article used for food in a form in which the food has not been chemically altered". The FDA is then able to evaluate whether it is reasonably expected to be safe.

Color and Food Additive Petitions:

Colors additives used in food, drugs, cosmetics or medical devices must be certified as safe by the FDA's Office of Food Additive Safety. 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.

Acidified and Low-Acid Canned Foods Registrations:

Companies must register and file their acidified canned food (AF) or low-acid canned food (LACF) prior to manufacturing, processing and packing the product.

Infant Formula Notifications:

The safety of infant formulas in the U.S. is regulated by FDA and as such a manufacturer must notify FDA 90 days before the first processing of any infant formula that differs fundamentally in processing or in composition from any previous formulation produced by the manufacturer. This includes significant revisions, additions, or substitution of a macronutrient, for which the manufacturer has not had previous experience. Quality Control Procedure regulations establish testing requirements for infant formulas which undergo changes in ingredients or processing conditions that could affect the level of nutrients.

Pharmaceuticals:

IND, or Investigational New Drug Applications:

INDAs are required for all new molecules that are eventually intended for use in human pharmacology products, and have already been screened in animals. Once the legal status is changed to INDA under the FD&C it requires an application process which includes preclinical data which shows the product is safe for testing in humans; information on the manufacturer, composition and stability for manufacturing as well as protocols which will be used in the clinical studies to assess whether subjects will be exposed to unnecessary risks.

NDA, or New Drug Applications:

Drug sponsors may petition the FDA for approval of a new pharmaceutical for sale and marketing in the U.S. through a New Drug Application using the data gathered during the animal studies and human clinical trials. Via a 505(b)(2) application, the NDA allows the usage of agency findings for a previously-approved drug and published literature and allows the FDA to determine whether the benefits of a drug outweigh the potential risks, whether the proposed packaging and insert is appropriate and whether manufacturing methods allow for adequate preservation of identity, strength, quality and purity.

ANDA, or Abbreviated New Drug Applications (for Generics):

Generic drug applications are "abbreviated" because they are generally not required to submit preclinical and clinical data to establish safety and effectiveness. Instead, generic applicants must demonstrate bioequivalence.

DMF, or Drug Master Files:

A Drug Master File submission provides detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drugs. The information contained in the DMF may be used to support an IND, NDA, ANDA, another DMF, an Export Applications.

Structured Product Labeling - Establishment Registration and Product Listings (SPL):

The SPL is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a way to exchange product and facility information for pharmaceutical establishment and product registration.

Citizen Petitions:

Through a Citizen Petition (CP) Process, the FDA can be petitioned to amend a drug monograph either during development or after final publication. For the petition to be considered, submitted data must include information that demonstrates that a product is generally recognized among scientific experts as safe and effective.

Medical Devices:

Investigational Device Exemptions (IDE):

An IDE allows an investigational device to be used in a clinical study to determine its safety and effectiveness, often in support of a PMA. Once an IDE is approved, the device can be shipped for use in the trials without the other requirements for medical devices as specified in the FD&C.

510(k) Submissions for Medical Devices:

Premarket Notification (510(k)) submissions for medical devices are required by FDA to ensure that products are safe for use. They are reviewed by, the Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostics and Radiological Health (OIR) which fall under the CDRH.

Premarket Approvals (PMA):

A Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices, that support or sustain life. It is the most stringent of device marketing requirements by FDA.

Establishment Registrations and Product Listings:

Those who produce and distribute medical devices intended for use in the U.S. must register annually with the FDA. Most who are required to register 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. 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.

Colors for Cosmetics:

Colors for FDA Certification:

Color additives are subject to FDA approval, and in some cases each batch must be certified by the FDA, 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. Foreign color manufacturers must also have a U.S. agent.



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