FDA Submission Services

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.

The FDA has established a wide variety of product submission requirements across the food, dietary supplement, drug and medical device segments. Whether you are seeking assistance with an ANDA, DMF, 510(k), GRAS/NDI or a color certification, EAS Consulting Group is a valuable partner in the development and execution of an effective regulatory filing plan to achieve a successful submission. Our team of experts will work with you throughout the product development and submissions lifecycle to help you identify the regulatory requirements, assemble product dossiers, evaluate the studies and draft the required submissions documents (in proper eCTD templates and formats) to give your file the best advantage for successful review by the FDA. We can also assist in maintaining the required facility registrations and product listings. EAS provides assistance at every stage of the process, and works as a US Agent for those foreign based firms requiring this service.

EAS offers detailed assistance for FDA submission requirements:

Foods/Dietary Supplements

- ✓ "Generally Recognized As Safe" (GRAS)
- ✓ 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
- ✓ Structure/Function Claim Notifications

Pharmaceuticals

- ✓ Investigational New Drugs (IND)
- ✓ Abbreviated New Drug Applications (ANDA)
- ✓ 505(b)(2) Applications
- ✓ Drug Master Files (DMF)
- ✓ Structured Product Labeling (SPL)
- ✓ Citizen Petitions (CP)
- ✓ New Animal Drug Applications (NADA)
- ✓ Abbreviated New Animal Drug Applications (ANADA)

Medical Devices

- ✓ Investigational Devices (IDE)
- ✓ 510(k), DeNovo, PMA, and Premarket Notifications
- ✓ 513(g) and Pre-Submission Applications
- ✓ Establishment Registrations and Product listings

Colors for Cosmetics

- ✓ Colors for FDA Certification

EAS Consulting Group, LLC
www.easconsultinggroup.com

EAS Consulting Group, LLC can make recommendations and provide assistance with FDA submissions for your product(s). With scientific experts in toxicology, radiology, chemistry and biology and authorities in government laws and regulations, EAS' Independent 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/Dietary Supplements:

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.

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 an 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:
Color 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.

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 for which they are making claims in accordance with 21 CFR 101.93.

Pharmaceuticals:

Investigational New Drug Applications (IND):
IND Applications are required for all new molecules that are intended for use in human drug and biological products. Prior to filing an IND Application, a sponsor must have Chemistry, Manufacturing, and Controls information, a rationale for the development of the active entity, initial evidence of efficacy in animals, and safety information from animal studies conducted under Good Laboratory Practice regulations. When a company is ready to test its product in humans, an IND Application must be filed. The application 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.

505(b)(2) New Drug Application:
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 developed 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. The NDA 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 generally are 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, and 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. This is an essential step in properly listing drug products.

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.

NADA (New Animal Drug Applications) and ANADA (Abbreviated New Animal Drug Applications):
A new animal drug is defined, in part, as any drug intended for use in animals other than man, including any drug intended for use in animal feed but not including the animal feed, the composition of which is such that the drug is not GRAS and effective for the use under the conditions prescribed, recommended, or suggested in the labeling. An ANADA is used to seek approval for a generic NADA and includes any subsequent supplements to an approved ANADA.

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:
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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