Regulatory Support for Food and Drug Law Firms

Specializing in FDA Regulatory Matters

EAS Consulting Group

A Certified Group Company

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 applicable regulations. Employing a unique team of former FDA, USDA and state agencies officials and industry experts, many with more than 30 years of experience, EAS has the unparalleled expertise to assist clients with all of their consulting needs.

Whether your firm is looking for an expert witness in litigation involving FDA requirements, policies, and procedures; remediation, warning letters and 483 responses, or assistance with the preparation and submission of regulatory documents, audits and investigations, EAS senior consultants with both FDA and high-level industry experience can provide valuable assistance.

Examples of Support Areas:

- ✓ Expert Witness
- ✓ Remediation, Warning Letters, and 483 Responses
- ✓ Due Diligence
- ✓ Label and Claim Review
- ✓ GRAS and Food Contact Notifications
- ✓ New Dietary Ingredients (NDI)
- ✓ Pre-Market Approvals (PMA), Investigational Device Exemption (IDE), Investigational New Drug (IND), New Drug Application (NDA), Drug Master File (DMF) and more
- ✓ Novel Foods, Novel Food Ingredients, New Food Additives
- ✓ Labeling Advertising Assistance
- ✓ Facility and Product Registration and Listing
- ✓ Consent Decrees Remediation
- ✓ Import and Export Assistance
- ✓ Product Classification
- ✓ Adverse Event Reporting Assistance and Tracking
- ✓ Recall Management Plans and Executions

EAS Consulting Group, LLC provides food and drug attorneys a full spectrum of consulting services in all matters of regulatory compliance including expert witness, administrative submissions, facility audits, and label and claim reviews.

We have an extensive staff and Independent Consultant network of scientists with medical, nutrition, chemistry, microbiology, toxicology, and entomology backgrounds; and compliance officials with comprehensive knowledge of federal and state regulations and compliance procedures.

Expert Witness

EAS has provided thousands of hours in expert witness preparations and testimony for each of the FDA regulated industries. Our expert consultants, former FDA officials and high-level industry leaders, draw on their professional experience to provide expert opinions on FDA requirements, policies, and procedures. Their opinions help companies prepare for and defend against lawsuits regarding health and medical claims, structure/function claims, product safety and efficacy, manufacturing procedures, and many others.

Remediation and Consent Decrees

In the event that FDA issues a 483 or warning letter or the Department of Justice files a consent decree, EAS can assist with a timely and appropriate response. EAS also assists as a third-party expert for review, audit, and evaluation of facilities and documentation, and can formulate a remediation plan and response in compliance with FDA requirements.

Our experts are former FDA inspectors with strong regulatory backgrounds, specially trained in FDA regulations. For example, our seafood auditors are experts in the principles of Hazard Analysis and Critical Control Point (HACCP), and our drug and dietary supplement auditors are experts in understanding the applicable regulatory requirements. EAS auditors are available to conduct facility audits throughout the drug, medical device, food, dietary supplement, tobacco, and cosmetic industries.

Submissions

Our team of drug and device experts, toxicologists, food scientists, and medical experts is available to guide you through the complex regulatory process. By seeking our advice early, we can outline the quickest, least expensive route to satisfy the applicable marketing requirements. Our scientific staff is internationally known for their expertise in conducting safety reviews and in gaining approvals from FDA and other regulatory bodies. We will review your client's situation and make recommendations on the available options. We will map out a strategy for compiling the necessary data and, where necessary, submit a letter, GRAS, FCN or NDI notification, NDA, DMF or other data package to the FDA. We are available to convene expert panels to conduct an independent safety evaluation of a food, color, or dietary ingredient when needed.

Due Diligence

EAS is staffed with former FDA investigators and industry auditors that are available to audit firms that your clients are either considering purchasing or have an interest in having contract work performed by. Before they invest in such a firm, EAS can assess their current level of compliance with FDA Good Manufacturing Practice regulations and identify what it will take to bring these facilities into compliance. By having EAS on their due diligence team, costly mistakes can often be avoided.

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