Foods, Including Seafood, LACF and Infant Formulas

Specializing in FDA Regulatory Matters

EAS CONSULTING GROUP

EAS Consulting Group, LLC is a leading provider of regulatory services to FDA regulated industries. With more than 50 years of experience assisting clients in developing regulatory strategies, implementing quality assurance programs, filing regulatory submissions and ensuring compliance with FDA regulations, EAS is poised to assist food firms with the many requirements for food safety placed upon them. From regulatory training, to the development and submission of GRAS notices, to preparations for the Food Safety Modernization Act, EAS Independent Consultants provide much needed expert guidance in all areas of the regulations of food. Our unique team of former Food and Drug Administration (FDA) officials and industry experts, many of whom have more than 30 years of food quality and safety experience are recognized leaders in their fields and provide a unique perspective on the agency's requirements.

Choose EAS to help your firm with:

Food Safety Modernization Act Food Safety Plans:

- ✓ FSMA Readiness Assessments
- ✓ Preventive Controls for Human Food (PCHF)
- ✓ Preventive Controls for Animal Food (PCAF)
- ✓ Qualified Individuals for Food Supplier Verification Program (FSVP) and Preventive Controls
- ✓ Food Safety Plans
- ✓ Documentation and Record Keeping Practices
- ✓ Quality Program
- ✓ Traceability and Recall Program
- ✓ Allergen Controls

Submissions Services:

- ✓ "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
- ✓ AF and LACF Registrations
- ✓ Infant formula Notifications

Labeling and Claims:

- ✓ Label Reviews
- ✓ New Nutrition Facts Panel Requirements
- ✓ Packaging and Marketing Claims Review

EAS Consulting Group, LLC
www.easconsultinggroup.com

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.

Developing Regulatory Strategies

Whether you need assistance with submissions, labeling and claims; have questions about the safety of a food or ingredient; need assistance in performing internal audits and FSMA Readiness Assessments, or need help in setting up your quality systems, we have food safety plan experts to help.

Our Independent Consultants consist of labeling experts; scientists with medical, nutrition, chemistry, microbiology, toxicology, and entomology backgrounds; and compliance officials with detailed knowledge of federal/state regulations and compliance procedures.

Submissions

EAS can prepare and submit data to support:

- "Generally Recognized as Safe" (GRAS)
- Structure/Function Claims Notifications
- Food Facility Registrations
- New Dietary Ingredient (NDI) Notices
- Color and Food Additive Petitions
- Acidified and Low-Acid Canned Foods Registrations
- Infant Formula Notifications

Auditing Services

Companies throughout the world are finding EAS auditing services to be unparalleled. Our auditors are available to travel to your manufacturing, warehouse, or retail facilities anywhere in the world. Our auditors are typically former FDA inspectors with strong regulatory backgrounds, who can conduct facility audits including Good Agricultural Practice (GAP) audits, seafood HACCP audits, Low Acid Canned Food (LACF) audits and Good Manufacturing Practice (GMP) audits. Our assessments are thorough and complete. You will receive a detailed report outlining your current level of compliance with each section of the GMP rule with our recommendation as to what needs to be done to bring identified deficiencies into compliance.

Labeling and Claims

FDA has established specific requirements as to how conventional foods and dietary supplements must be labeled and has defined what they consider to be allowable claims for these products. EAS Independent Consultants, former high level FDA officials, helped develop these regulations and have an "insider's" perspective on how the Agency interprets them. Our consultants are available to review current and proposed labeling for formatting, nutrition information, and assist you in developing claims that will comply with FDA requirements.

Food Safety Modernization Act (FSMA)

The Food Safety Modernization Act is the largest change the food industry has seen since the inception of FDA. FSMA legislation was designed to strengthen the safety of the U.S. food supply by requiring preventive controls at all levels, from the grower, supplier, manufacturer, distributor, importer and so on. EAS provides a full spectrum of consulting services with regards to FSMA.

Seminars and Onsite Training

EAS takes pride in our ability to conduct training courses tailored to meet the needs of your organization. Whether the training takes place in-house with a customized agenda, or you travel to one of EAS public trainings, you will hear a thorough analysis and review of current industry regulations. Students who have attended our programs have found EAS trainings to be unique, in that they have an opportunity to ask former regulators questions that simply cannot be addressed by other training organizations.

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