FDA-Regulated Industry Services

Specializing in FDA Regulatory Matters

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, the firm has 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. Employing a unique team of former Food and Drug Administration (FDA) officials and industry experts, EAS offers unparalleled expertise with many consultants having more than 30 years of FDA experience.

EAS services include:

- ✓ Consulting
- ✓ Submissions
- ✓ Auditing
- ✓ Training
- ✓ Product Development and Label Assistance
- ✓ Law Firm Services
- ✓ US Agent and Import Services
- ✓ Food
  - » Produce
  - » Dairy and LACF
  - » FSMA
  - » Retail Food Protection
- ✓ Pharmaceuticals
- ✓ Dietary Supplements
- ✓ Tobacco
- ✓ Medical Device
- ✓ Cosmetics
- ✓ State Regulated Industry

EAS CONSULTING GROUP

EAS Consulting Group, LLC
www.easconsultinggroup.com

Consulting:

EAS provides a full spectrum of consulting services in all FDA regulated industries as well as some USDA, state-regulated industries and more. Our Independent Consultants, internationally recognized as thought leaders in their particular areas of expertise, have decades of experience in high-level FDA and industry positions and have accumulated the knowledge, expertise and experience you need to ensure accurate, thorough assessment of your regulatory needs as well as an action plan to move forward.

Whether you need assistance with labeling and claims, Good Manufacturing Practices, submissions filing, questions on safety or stabilities studies or need US Agent representation, EAS Consulting Group, with our over 150 Independent consultants will provide the experience and expertise you are looking for. Our consultants consist of labeling experts, toxicologists, microbiologist, entomologists, food scientists, chemists, former FDA inspectors and more.

Submissions:

The safety of pharmaceuticals, medical devices, food/color additives and cosmetics ingredients, Generally Recognized as Safe (GRAS), New Dietary Ingredients (NDI) must all be established prior to the product entering the US marketplace.

Requirements of safety data and other regulatory approvals must be met in certain cases and those requirements vary. Our expert team is able to guide your company through the complex processes and by seeking guidance early, EAS can outline the quickest and least expensive route to satisfy applicable safety substantiation requirements. EAS is internationally known for our success at filing submissions and gaining FDA approvals on behalf of clients. Mapping out a strategy of data compilation and filing a submission of GRAS or NDI notifications, 510(k), NDA, DMF, establishment and facility registration and any other data packet to FDA. We are also able to convene expert panels to conduct independent safety evaluations of foods, color, food additive and dietary supplement ingredient as needed.

Auditing:

Companies around the world find EAS auditing and mock-FDA inspections to be of unparalleled value. Our Independent Consultants, former auditors and FDA inspectors, offer a variety of options from "desk audits" to in-person detailed inspection of your manufacturing, retail and storage facilities. With the industry's reliance on qualified third-party auditing firms, there is increased demand for services auditing services such as Good Agricultural Practices, Hazard Analysis and Critical Control Points (HACCP), Low-Acid Canned Food (LACF), Good Manufacturing Practices (GMPs) and others.

Training:

EAS prides itself on expertise and excellence in our regulatory compliance seminars and on-line training programs. Whether attending a publicly offered training or bringing EAS in-house to provide a tailored program specific to your own training needs, EAS is recognized as an leading training firm in regulatory compliance. Students who attend EAS trainings find them unique in that they are able to learn from former FDA regulators and ask questions that simply cannot be addressed by other training organizations.

Product Development and Label Assistance:

EAS' strategic Product Development and Labeling consulting service provides solutions to companies confronting the challenging issues of food product development. By taking a holistic approach that considers marketing objectives and the current regulatory, compliance, and enforcement environment at the federal, state and local levels, EAS assists clients from ideation through commercialization. Our international team of consultants can also assist US-based clients wishing to export.

EAS labeling team is highly trained in FDA and USDA requirements as well as that of the EU and Canada. EAS can both review labels for accuracy and claims or create new labels with your company data.

Law Firm Services:

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.

US Agent and Import Services:

EAS Consulting Group provides registration and listing assistance as well as U.S. 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 U.S. marketplace as quickly as possible.

EAS CONSULTING GROUP
FDA-Regulated Industry Services 0002

EAS Consulting Group, LLC
1700 Diagonal Road, Suite 750
Alexandria, Virginia 22314
(571) 447-5500

For more information contact
Ed Steele at (571) 447-5501- esteele@easconsultinggroup.com
Dean Cirotta at (571) 447-5502- dcirotta@easconsultinggroup.com