Food Product Development and Labeling Strategic Consulting

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 EAS strategic 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.

Developing proactive solutions for:

- ✓ GMO Labeling
- ✓ "Natural" Foods and Claims
- ✓ Undefined Claims
- ✓ New Threats Posed by FDA Warning Letters
- ✓ FTC v. FDA
- ✓ Trending Claims
- ✓ Nutrition Labeling
- ✓ Competitive Challenges
- ✓ Crisis Management
- ✓ Long Term Planning
- ✓ Submissions Assistance
- ✓ In-House Training

EAS Consulting Group, LLC
www.easconsultinggroup.com

EAS Consulting Group, LLC provides all the strategic consulting, auditing, training and submission assistance you need to market fully compliant food products in the United States.

Proactive Solutions

EAS works directly with agencies to effectuate change; filing official comments as necessary to the appropriate departments and agencies. Our extensive contact network, through third-party outreach efforts, will help to build alliances and achieve company objectives.

- ✓ **GMO Labeling** – Should companies disclose GMO ingredients, create a "non-GMO" product line, or stay the course? How should such disclosures be made?
- ✓ **"Natural" Foods and Claims** – What are the risks of self-defining "natural" foods including the risk of class action litigation challenging such claims? What approaches to labeling and advertising can minimize these risks?
- ✓ **Undefined Claims** – How can companies make undefined claims such as "Handcrafted," "Real" and "Authentic" while minimizing risk from federal and state regulatory authorities as well as the risk of a class action law suit?
- ✓ **New Threats Posed by FDA Warning Letters** – How can companies prevent a FDA warning letter from triggering "pile on" actions by state attorneys general and plaintiff class action attorneys?
- ✓ **FTC v. FDA** – When does compliance with FDA labeling regulations for structure/function and other claims constitute compliance with FTC enforcement policy regarding food and dietary supplement advertising?
- ✓ **Trending Claims** – What are they and how can companies minimize regulatory and litigation risk when using them?
- ✓ **Nutrition Labeling** - How can companies formulate products so as to stay a step ahead of the new disclosure requirements? What opportunities are presented in connection with the new criteria for disclosing "added sugars," dietary fiber, and serving size?
- ✓ **Competitive Challenges** – How can companies leverage regulatory requirements in challenging competitors? What is the best path toward agency engagement?

Crisis Management

When problems arise, the EAS strategic consulting group will mobilize as a government and public affairs "S.W.A.T." team, providing real time support for a client's response to crisis management situations. Our team will prepare and deliver persuasive, data-driven counter messaging in both traditional media and social media forums. Our team will utilize relationships with today's opinion leaders including health professionals, academics, and journalists to deliver positive messages to create a fact-based dialog and bring a crisis situation under control.

Long Term Planning

Once a crisis is under control, the EAS strategic consulting group can carefully develop a long-term communications and strategic regulatory compliance plan designed to shift the tide of public opinion and protect a company's reputation and brands.

Submissions Assistance

Should your product or new ingredient require a FDA submission such as Generally Recognized as Safe (GRAS), New Dietary Ingredient (NDI) or color and food additive petition, EAS can make recommendations and provide assistance with FDA submissions for your product(s). With scientific expertise in toxicology, radiology, chemistry and biology as well as authorities in government laws and regulations, EAS consultants can lead your company through the process of obtaining necessary background data, filing submissions, and following-up as needed during the submission process. EAS experts can also provide guidance respecting competitive challenge situations, including assistance with submitting a claims matter to the National Advertising Division of the Council of Better Business Bureaus.

In-House Training

EAS takes pride in our ability to conduct training courses tailored to meet the needs of your organization, including these very challenging questions of product development. Whether the training takes place in-house with a customized agenda, or you travel to one of EAS's public trainings, our consultants, former FDA, USDA, state and industry experts, will provide a thorough analysis and review of the current industry regulations. Students find 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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