Dietary Supplement Services

Specializing in FDA Regulatory Matters

EAS CONSULTING GROUP

EAS Consulting Group, LLC is a leading provider of regulatory consulting services to the dietary supplement industry for adherence to the Dietary Supplement Health and Education Act (DSHEA) of 1994 which was passed by the United States Congress in 2007. The law provided for structure/function and health claims on dietary supplements and authorized the Food and Drug Administration (FDA) to issue and enforce Good Manufacturing Practices (GMPs) dictated in 21 CFR 111, Current Good Manufacturing Practices in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. The FDA also requires ingredients used for the manufacture of dietary supplements to be Generally Recognized as Safe (GRAS) or accepted for use through a New Dietary Ingredient (NDI) Notification. As a classification of foods, dietary supplement product labels must comply with the detailed instructions given in 21 CFR 101, Food Labeling. In addition, serious adverse events associated with the use of dietary supplements must be reported to the FDA in accordance to the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 – Serious Adverse Event Reporting. The unique EAS team of former FDA officials and industry experts, most with more than 30 years of experience, offers unparalleled expertise to guide clients through all of these regulatory requirements and ensure compliance with the law.

- ✓ Develop Regulatory Strategies
- ✓ Structure/Function and Health Claims
- ✓ GRAS Submissions
- ✓ NDI Notifications
- ✓ Dietary Supplement Labeling
  - » Training
  - » Review
- ✓ Good Manufacturing Practice Training
- ✓ Facility Auditing
  - » Gap Analyses
  - » Mock-FDA Inspections
  - » Contractor Audits (Manufacturers, Packagers, Distributors and Laboratory)
- ✓ Quality System Development
- ✓ Standard Operating Procedure (SOP) Writing
- ✓ Establishment of Specifications
  - » Raw Material
  - » In-Process
  - » Finished Product
- ✓ Stability Program Development
- ✓ Quality Agreement Preparation
- ✓ Regulatory Remediation
  - » 483 Observation Response
  - » Warning Letter Response
  - » Consent Decrees
  - » Corrective and Preventative Action (CAPA) Plans and Implementation
- ✓ Expert Witness

EAS Consulting Group, LLC
www.easconsultinggroup.com

Regulatory Strategies

Our consultants have spent a good portion of their professional career working at FDA and/or working in industries regulated by the Agency. We have scientists with medical, nutrition, chemistry, microbiology, and toxicology backgrounds; and compliance officials with detailed knowledge of federal/state regulations and compliance procedures. It is this first-hand experience that sets EAS apart from others in this industry. We can assist you in planning new product development, including how the product will need to be labelled, how to make legal claims, how to comply with FDA notification requirements and help you ensure that your manufacturing and laboratory resources are fully compliant with all FDA regulations.

Structure/Function and Health Claims

DSHEA requires that the FDA be notified of structure/function claims and that these claims are based upon scientifically valid evidence. EAS can assist you in designing studies that will substantiate the claims made for your product and then notify the FDA of such claims. Health claims are allowed only when a product meets specifications designated by the FDA. Our Independent Consultants can ensure that your product health claims comply with FDA requirements.

GRAS Submissions

GRAS submissions are required under section 201(s) and 409 of the Federal Food, Drug, and Cosmetic (FD&C) Act. Any substance that is intentionally added to a food is a food additive, and these are subject to premarket review and approval by the 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.

NDI Notifications

A manufacturer or distributor of an NDI, or dietary supplement that contains an NDI, is required to submit a premarket notification to the 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 the NDI is reasonably expected to be safe. Our expert Independent Consultants can assist you with the determination of whether a dietary ingredient meets this pre-DSHEA requirement, and if not, designing the studies that are necessarily to support an NDI notification to the FDA.

Dietary Supplement Labeling

The FDA has established specific requirements as to how dietary supplements must be labeled. Our Independent Consultants are available to review current and proposed labeling for both formatting and nutrition information. We also provide webinars, public training courses, and onsite training programs to meet the labeling needs of your organization.

Good Manufacturing Practice Training

The GMPs dictated in 21 CFR 111 have been in place for over a decade, but the FDA continues to issue numerous Warning Letters to the industry for a failure to comply with even the basic tenants of the regulation. Ensure that this does not happen to your organization by providing the essential, initial and annual follow-up GMP training to your personnel. EAS provides webinars, public training courses, and onsite GMP training programs that can be tailored to meet your needs. Students that have attended EAS training programs have found them to be extremely beneficial and we consistently get feedback that our trainings are the "best."

Facility Auditing

EAS has former FDA investigators, laboratory personnel, and industry quality experts available to conduct thorough and complete GMP audits of your onsite or contractor manufacturing, packaging, distribution, and laboratory facilities to assess compliance with 21 CFR 111 as well as other applicable statutory requirements. We can conduct these audits as an open communication gap analysis to let you know what improvements are needed to become fully compliant, or as a mock-FDA inspection that can be used as both a training mechanism for your personnel and facility compliance assessment. Upon conclusion of the audit, you will receive a detailed report listing all of the observations found and recommendations as to what corrective and preventative actions (CAPAs) must be taken to bring the identified deficiencies into compliance.

Quality System Development

GMPs are by definition a system of procedures and documentation, written or analytical, to ensure the product produced has the identity, strength, quality, and purity which it purports or is represented to possess. In 21 CFR 111 there are a number of written procedures, required documents, and records that must be developed and maintained to minimally comply with the regulation. The vast experience of our EAS Independent Consultants will help you to not only comply with these requirements but also develop a strong quality system that is also practical and efficient.

Standard Operating Procedure (SOP) Writing

Written procedures, or SOPs, are critical documents that serve as guidance for company policy, standardize processes, maintain continuity among employees, reduce confusion and uncertainty, and are used as a vehicle for training and instruction. SOPs also authorize, define, and set controls for all required subordinate document systems such as Master Formulations, Master Manufacturing Records, and Specifications. Yet, writing (or having the time to write) a good SOP is a unique skill that is often not available at many organizations. Our consultants have decades of experience writing and reviewing SOPs and are here to assist you to ensure that all SOPs are clear, concise, complete, correct, and compliant.

Establishment of Specifications

A failure to establish specifications in accordance to 21 CFR 111.70 and determine whether these specifications have been met per 21 CFR 111.75 has contributed to more than 50% of the FDA observations since compliance with the regulation was required for all companies in 2010. Raw material, in-process material, and finished product specifications must address the quality aspects of identity, purity, strength, composition, and limits of potential contaminants. Creating these specifications requires significant knowledge about the type of material or product, as well as scientific expertise regarding the test methods available for use, particularly as it pertains to complex dietary supplements and raw materials, such as botanical ingredients. Let our expert scientific consultants assist your organization with the preparation and use of appropriate specifications.

Stability Program Development

The use of an expiration date on a dietary supplement product is voluntary under DSHEA, but "any expiration date or equivalent term you place on a product label should be supported by data that demonstrates the product's shelf life." EAS can assist with the development of dietary supplements formulations using appropriate overages and the establishment of a stability program to ensure that the product meets 100% of label claim for all ingredients throughout the product shelf life as required in 21 CFR 101.

Quality Agreement Preparation

The dietary supplement industry is an industry of contracting and sub-contracting. However the brand owner or Own Label Distributor (OLD) is responsible for ensuring that the product was produced using GMPs regardless of who performed manufacturing, packaging, labeling, holding, distribution, and laboratory operations. Establishing a comprehensive Quality Agreement between parties will ensure that all quality requirements dictated in 21 CFR 111 have been assigned and will be performed by the appropriate responsible party. EAS has prepared a large number of these agreements and can help prepare them specific to your organizations contractual relationships.

Regulatory Remediation

EAS's team of former FDA investigators and industry quality experts can assist should your company receive an FDA-483, Inspectional Observations form or Warning Letter upon facility inspection or company website and social media review. There is a 15-business day time frame in which to respond and EAS can help interpret the findings, assist in formulating an effective corrective and preventative action plan, and preparing the official response to the FDA. Follow-up communications with the Agency can also be generated and/or reviewed by our team prior to submission.

Expert Witness

Given our expertise and experience, EAS Advisors and Executives can also serve as expert witnesses if the situation arises.

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