Dietary Supplement Retail Industry Services

Specializing in FDA Regulatory Matters

EAS Consulting Group

A Certified Company

Retailers and Own Label Distributors of food, dietary supplement, and pharmaceutical Over the Counter (OTC) products have a unique set of challenges. From supply chain and contract manufacturer management, to transportation and storage requirements; from own label product claims and marketing to Food Safety Modernization Act (FSMA) legislation; and the development of internal quality management systems to control and document it all. Dietary supplement and pharmaceutical OTC companies also have the responsibility of establishing product specifications and overseeing product testing to verify product quality. Retailers and Own Label Distributors are touched by every level of compliance to relevant Good Manufacturing Practice (GMP) regulations as well as other applicable statutory requirements.

EAS Consulting Group, LLC understands the unique and complex challenges facing Retailers and Own Label Distributors. EAS is a leading provider of regulatory services to FDA and USDA regulated industries, with more than 50 years of experience assisting clients in developing regulatory strategies, implementing quality systems, and assisting contract manufacturers with compliance to FDA regulations. EAS Independent Consultants are a unique team of former State regulatory officials, FDA and USDA officials and industry experts, many of whom have more than 30 years of food, dietary supplement, and pharmaceutical OTC experience.

Choose EAS for:

- ✓ FSMA Readiness Assessments
- ✓ Labeling Compliance
- ✓ Quality System Development
- ✓ Establishing Finished Product Specifications
- ✓ Quality Agreement Preparation
- ✓ Supplier Qualification
- ✓ Contractor Audits
  - » Manufacturers
  - » Packagers
  - » Distributors
  - » Laboratory
- ✓ Personnel Training
- ✓ Emergency Planning
  - » Natural Disasters
  - » Defense and Fraud Protection
- ✓ Complaint Handling
  - » Serious Adverse Event Reporting
  - » Recalls
- ✓ Regulatory Remediation
  - » FDA-483 Observation Response
  - » Warning Letter Response
  - » Corrective and Preventative Action (CAPA) Plans and Implementation
- ✓ Seminars and Onsite Training

EAS Consulting Group, LLC is a leading provider of regulatory services to the food, dietary supplement, pharmaceutical, medical device, 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.

FSMA Readiness Assessments

EAS provides FSMA Readiness Assessments which consist of a thorough company review and evaluation of policies, procedures, and records required to meet the unique, detailed demands of the FSMA legislation. The CDC and FDA model Food Code provides the framework of retail food regulatory requirements across the US. Each state may adopt all or portions of the Code as well as add supplemental regulatory requirements. In addition, states may have adopted earlier versions of the model code. The end result is a patchwork of retail food regulatory requirements. The EAS team understands this and can assist in developing unifying practices and standards that are applicable state to state.

Labeling Compliance

FDA has established specific requirements as to how food, dietary supplements, and pharmaceutical OTC products must be labeled and has defined what they consider to be allowable claims for these products. EAS Independent Consultants are available to review current and proposed labeling for formatting, nutrition information, and the development of claims that will comply with FDA requirements. They can also assist in designing studies that will substantiate the claims made for your products.

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. There are a number of written procedures, required documents, and records that must be developed and maintained to minimally comply with the applicable regulation. The vast experience of our EAS consultants will help you to not only comply with these requirements but develop a strong quality system that is also practical and efficient.

Establishing Finished Product Specifications

The FDA requires that dietary supplement and pharmaceutical OTC Own Label Distributors establish finished product specifications in order to demonstrate that each manufactured batch of product meets quality requirements for identity, purity, strength, composition, and limits of potential contaminants. Creating these specifications requires significant knowledge about the product formulation and manufacture, as well as scientific expertise regarding the test methods available for use, particularly as it pertains to complex dietary supplements that contain botanical ingredients. Let our expert scientific consultants assist your organization with the preparation and use of appropriate specifications.

Quality Agreement Preparation

Retailers and Own Label Distributors (OLD) are responsible for ensuring that the product it places into the consumer market 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 the applicable regulation 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.

Supplier Qualification

EAS Independent Consultants are experienced in both the wholesale and retail food industries. This experience is advantageous when assessing the food chain from the point of receiving at your distribution center and downstream to your retail stores. Dietary supplement and pharmaceutical OTC companies are required to develop and implement a rigorous supplier qualification process to be in regulatory compliance. Our many expert consultants in these industries have extensive, first-hand experience doing so, and can assist you with the development of a program that suits the needs of your, unique combination of quality systems, personnel, products, and suppliers.

Contractor Audits (Manufacturers, Packagers, Distributors and Laboratory)

EAS has former FDA investigators, laboratory personnel, and industry quality experts available to conduct thorough and complete audits of your on-site or contractor manufacturing, packaging, distribution, and laboratory facilities to assess compliance with all applicable GMPs 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.

Emergency Planning

Business continuity is critical to survival across all business platforms. Natural disasters, intentional contamination, or food fraud can impact your operations. Minimizing any interruption of your services is vital to your brand and possibly the survival of your company. EAS can assist you in making sure your company is prepared. Our experts have first-hand experience responding to the retail sector after natural disasters and are experts in retail food defense. EAS can help your business to prevent, respond and recover from such emergencies.

Complaint Handling

Handling consumer complaints is something that every industry has to deal with, but in an FDA regulated environment there are very specific regulatory and legal requirements that must be fulfilled. All complaints must be evaluated and categorized, and those that are defined as Serious Adverse Events (SAE) must be promptly reported to the FDA for agency investigation. Recalls are a unique challenge for the retail industry since products are either one step away from the consumer or have already been purchased by the consumer. Both the FDA and States conduct recall effectiveness checks. EAS can assist in developing, executing and evaluating your complaint handling, SAE reporting processes, and recall plans, including simple to complex annual mock recalls, to ensure compliance.

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.

There is an advantage to a one-stop-shop consulting services through EAS. Our team of pharmaceutical, OTC and Food experts have the expertise up-stream with manufacturers and distributors. An EAS team approach to ensuring compliance across company and retail lines, from food to pharmacy, cosmetic to household products provides peace of mind and ease of coordination

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