Dietary Supplement Services

Specializing in FDA Regulatory Matters

EAS Consulting Group

A Certified Group Company

EAS Consulting Group, as part of the Certified Group of companies, merged with Food Safety Net Services, (FSNS), to become the global leader in testing and regulatory solutions for the FDA and USDA regulated industries. We are 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 FDA to issue and enforce Good Manufacturing Practices (GMPs) dictated in 21 CFR 111. 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

NEED A TESTING PARTNER?

Trust the FSNS and Certified Group of Companies for all of your laboratory testing needs.

EXPECT MORE

FSNS Food Safety Net Services

Certified Group Laboratory Testing | Regulatory Consulting

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