Dietary Supplement Services

Specializing in FDA Regulatory Matters

EAS Consulting Group

A Certified Group Company

EAS Consulting Group is a leading provider of regulatory consulting services for adherence to the Dietary Supplement Health and Education Act (DSHEA).

Our experts develop Good Manufacturing Practices (GMPs) as dictated in 21 CFR 111, assist with development Supplement Facts Panels per 21 CFR 101, including structure/function and health claims, and support submissions to FDA for new 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.

Our unique team of former FDA officials and industry experts, most with more than 30 years of experience, offers unparalleled expertise to guide EAS clients through the many regulatory requirements placed upon the dietary supplement industry and ensure compliance with the U.S. Federal law.

- ✓ Regulatory Strategy Development
- ✓ Dietary Supplement Labeling
- ✓ Structure/Function and Health Claims
- ✓ GRAS and NDI Submissions
- ✓ Good Manufacturing Practice Training
- ✓ Facility Audits
  - » Gap Analyses
  - » Mock-FDA Inspections
  - » Contractor Audits (Manufacturers, Packagers, Distributors and Laboratory)
- ✓ Quality System Development
- ✓ Stability Program Development
- ✓ Standard Operating Procedure (SOP) Writing
- ✓ Establishment of Specifications
  - » Raw Material
  - » In-Process
  - » Finished Product
- ✓ Quality Agreement Preparation
- ✓ Regulatory Remediation
  - » 483 and Warning Letter Response
  - » CAPAs
- ✓ Expert Witness
- ✓ Seminars and Onsite Training

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