

# FDA Submission Services

*Specializing in FDA Regulatory Matters*



## EAS Consulting Group

A Certified Group Company

The FDA has a wide variety of product submission requirements. Whether you are seeking assistance with an ANDA, DMF, 510(k), GRAS/NDI or a color certification, EAS Consulting Group is a valuable partner in the development and execution of an effective regulatory filing plan to achieve a successful submission.

EAS' network of nearly 200 independent advisors and consultants enables us to provide comprehensive consulting, training and auditing services, ensuring proactive regulatory and quality compliance for all FDA regulated industries as well as hemp and CBD.

Our team of experts work with you throughout the product development and submissions lifecycle to help you identify the regulatory requirements, assemble product dossiers, evaluate studies and draft the required submission documents to give your file the best advantage for successful review by the FDA.

We can also assist in maintaining the required facility registrations and product listings. EAS provides assistance at every stage of the process, and works as a US Agent acting as a conduit of information for foreign firms that are marketing product in the U.S.

### Choose EAS For

#### Foods/Dietary Supplements

- ✓ "Generally Recognized As Safe" (GRAS)
- ✓ Food Facility Registrations
- ✓ New Dietary Ingredient Notices (NDI)
- ✓ Food and Color Additive Petitions
- ✓ Acidified and Low Acid Canned Food Registrations (AF and LACF)
- ✓ Infant formula Notifications
- ✓ Structure/Function Claim Notifications

#### Pharmaceuticals

- ✓ Investigational New Drugs (IND)
- ✓ New Drug Applications (NDA)
- ✓ Abbreviated New Drug Applications (ANDA)
- ✓ 505(b)(2) Applications
- ✓ Drug Master Files (DMF)
- ✓ Structured Product Labeling (SPL)
- ✓ Citizen Petitions (CP)
- ✓ New Animal Drug Applications (NADA)
- ✓ Abbreviated New Animal Drug Applications (ANADA)

#### Medical Devices

- ✓ Investigational Devices (IDE)
- ✓ 510(k), DeNovo, and Premarket Notifications
- ✓ 513(g) and Pre-Submission Applications
- ✓ Establishment Registrations and Product listings

#### Colors for Cosmetics

- ✓ FDA Color Certification

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