

# FDA Submissions for Human and Animal Food Ingredient and Packaging Safety



## EAS Consulting Group

A Certified Group Company

Before a substance can be legally added to food in the U.S., with rare exceptions, it must be either an approved food additive, through a Food Additive Petition (FAP), prior-sanctioned, or determined to be generally recognized as safe (GRAS) for use in food. This is applicable for both human food and animal food. FDA has the similar rigorous requirements for human food packaging materials through Food Contact Notifications (FCN), New Dietary Ingredient Notifications (NDIN) for dietary supplements, and Color Additive Petitions (CAP).

EAS Consulting Group, LLC has a long and successful history of leading companies through the GRAS, FAP, FCN, NDI, and CAP submission processes. Our 200 consultants include toxicologists, microbiologists, chemists, nutritionists, and regulatory experts design studies, analyze data, prepare submissions and more. EAS is the leading provider of regulatory services to the FDA and USDA regulated industries. We assist clients with developing regulatory strategies, implementing quality systems, filing regulatory submissions, and ensuring compliance with all FDA and USDA regulations.

### Choose EAS for:

- ✓ Expert project management from start to finish
- ✓ FDA and industry experienced consultants with extensive knowledge and understanding of regulatory requirements
- ✓ Feasibility and data gap assessments
- ✓ Study design and protocol development
- ✓ CRO identification
- ✓ Coordinating study initiation and management oversight with the CRO
- ✓ Monitoring of study protocols and outcomes
- ✓ Development of the submission dossier
- ✓ Determination of Estimated Daily Intake
- ✓ Allergenicity determinations
- ✓ Self-Determined GRAS conclusion
- ✓ Commissioning and leading Expert GRAS Panel reviews
- ✓ Coordination of timely FDA communications
- ✓ FDA submissions
  - » GRAS
  - » Food Additive Petitions
  - » Color Additive Petitions
  - » Food Contact Notifications
  - » New Dietary Ingredient Notifications

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