

FDA Foreign Supplier Verification Services

Specializing in FDA Regulatory Matters



US Food Safety Modernization Act (FSMA) import regulations offer a unique and complex challenge for any foreign food manufacturer or US food importer. With Food and Drug Administration's enforcement of the Foreign Supplier Verification Program (FSVP) program, US food importers and foreign food manufacturers are required to comply with regulations found in the Preventive Controls, Foreign Supplier Verification and the Nutrition Labeling and Education Act (NLEA) rules as well as laws and regulations imposed by US Customs and Border Protection (CBP) and US Biosecurity laws and regulations. These regulatory hurdles must be overcome in order to comply with the unified US government enforcement program on food imports.

EAS Consulting Group, with its highly skilled and experienced technical staff and over 150 Independent Consultants (many with work history with the US FDA), have the hands-on experience to assist both foreign food manufacturers and those importing foods to gain access to the US food market.

Not only does EAS have the expertise and capability in providing key regulatory services, we also have a number of FDA-recognized Foreign Supplier Verification Program (FSVP) "Lead Instructors" that can provide training and on-site assessment of a foreign supplier's food safety program. Through our affiliated U.S. Customs Agents, EAS can also address trade documentation requirements for imported foods.

Whether you need just a short phone call to answer your FSVP questions or a more significant set of EAS services such as how to be removed from the FDA "Import Alert List", EAS can assist with all regulatory challenges.

Choose EAS for:

- ✓ Setting up a US FSVP "Importer" office
- ✓ Educating FSVP Importers on "Qualified Individual" responsibilities and performing them on behalf of the FSVP Importer
- ✓ On-site Foreign Food Manufacturer and Warehouse Assessments
- ✓ FDA Foreign Food Manufacturer Registration
- ✓ Applying for and Receiving DUNS Number (required for FSVP Importer)
- ✓ On-site FSMA Preventive Controls and FSVP Training
- ✓ Building or Updating Preventive Control-Based Food Safety Plans for Foreign Manufacturers
- ✓ Traceability and Recall Assessment
- ✓ Desk Review of Written Food GMP Standard Operating Practices for Foreign Food Warehouses
- ✓ Food Labeling Compliance

EAS can assist foreign food manufacturers and their US FSVP "Importers" to identify all regulatory hurdles in advance of any interruptions, ranging from simple product holds at US ports to having FDA put the product and importer on the FDA "Import Alert" list, which blocks all imports of that specific food.

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

EAS provides a full spectrum of consulting services to the food industry. Our consultants have spent their professional careers working at FDA, USDA and State regulatory agencies or working in industries regulated by the States and FDA. It is this first-hand experience and expertise that sets EAS apart from others in this industry.

Consulting Services

Whether the question is safety, contract manufacturer compliance, internal or supplier auditing procedures, quality systems, or FSMA Foreign Supplier challenges, EAS has experts to help. Our team of FDA regulatory and labeling experts; scientists with medical, nutrition, chemistry, microbiology and toxicology backgrounds; and former FDA compliance officials with detailed knowledge of FDA, USDA and state laws and regulations as well as food import requirements and compliance procedures will provide the expert guidance you need for important regulatory requirements.

FSMA On-Site Assessment Services

EAS provides FSMA Readiness Assessments which consist of a thorough company review and assessment of which FSMA rules must be met, which documents, policies and procedures require updates as well as a regulatory pathway for meeting detailed demands of FSMA.

The CDC and FDA model Food Code provides the framework of regulatory requirements across the USA. 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 regulatory requirements across the USA. The EAS team understands this and can assist in developing unifying practices/standards that are applicable state to state. EAS can also assist in regulatory compliance and supplier qualification requirements.

EAS Independent Consultants are experienced in both the wholesale and retail food industries. This experience is advantageous when assessing the food chain from point of receiving at your distribution center and downstream to your retail stores.

Food Safety Plans

Protecting your food and your brand starts with a comprehensive Food Safety Plan, which is a requirement of FDA. Gaps in a Plan often lead to recalls and worse, such as foodborne disease outbreaks. EAS can utilize existing food safety written models to assist in updating or developing a new food safety plan that is compliant with the current FDA regulations.

Business Continuity & Crisis Management Plans

Business continuity and crisis management planning 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 after natural disasters and are experts in food defense. EAS can help your business to prevent, respond and recover from such emergencies.

Labeling and Claims

FDA has established specific requirements as to how food and dietary supplements must be labeled and has defined what they consider to be allowable claims for these products. EAS Independent Consultants helped develop these regulations and have an "insiders" perspective on how the Agency interprets them. Our consultants are available to review current and proposed labeling for formatting, nutrition information, and can assist you in developing claims that will comply with FDA requirements. Our consultants can also assist in designing studies that will substantiate the claims made for your product.

On-Site Assessments of GAP & GMPs/Quality Systems

EAS has former FDA, USDA and state investigators, laboratory personnel and industry quality experts available to conduct GMP/Quality Systems audits of your suppliers, contract manufacturing and laboratory facilities to assess compliance with applicable FDA and state regulatory requirements as well as established best practices. We are available to conduct gap assessments of these facilities to let you know what improvements are needed to become fully compliant with FDA and state requirements. Our assessments are thorough and complete. You will receive a detailed report outlining your current level of compliance with each section of the GMP rule, along with our recommendation as to what needs to be done to bring identified deficiencies into compliance.

Recall Readiness

Recalls are a unique challenge for the food industry since products are either one step away from the consumer or the consumer has already purchased the recalled product. Recall effectiveness checks are a must. And EAS can evaluate your recall plans and assist in developing, executing and evaluating a simple to complex mock recall.

Custom Training Programs

EAS takes pride in our ability to conduct training courses tailored to meet the needs of your organization. Whether the training takes place in-house with a customized agenda, or you travel to one of our public trainings, our consultants, former FDA, USDA, state and industry experts, will provide a thorough analysis and review of the current industry regulations. Students who have attended our programs have found EAS trainings to be unique, in that they have an opportunity to ask former regulators questions that simply cannot be addressed by other training organizations.



EAS Consulting Group, LLC
1700 Diagonal Road, Suite 750
Alexandria, Virginia 22314
(571) 447-5500

For more information contact
Allen Saylor at (571) 447-5509 - saylor@easconsultinggroup.com