

IMPORTING AND EXPORTING

FDA REGULATIONS AND COMPLIANCE

Are new FDA regulations holding up your shipments into the U.S.?
Livingston can help.

Importing and Exporting

FDA regulations and compliance

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FDA management and compliance is key

U.S. importers subject to Food & Drug Administration (FDA) regulations know that the “devil is in the details.” With recent high-profile recalls ranging from pet food to milk products, the FDA continues to take an active role in screening imports. Not only does this affect food products, but the FDA has a scope of operations that cover over 90 industries from pharmaceuticals and medical devices to radiation-emitting electronics and cosmetics. Due to ongoing vigilance, FDA-regulated imports are often delayed upon arrival to the United States simply because information requested by the government agency is inaccurate, incomplete or unavailable. Livingston can help.

Livingston’s proactive solution

Livingston International has a national FDA Compliance Team focused solely on the proactive management of FDA imports and their unique requirements. Our team’s dedicated resources review, monitor and manage all FDA data within Livingston’s import systems to improve its accuracy and availability before the shipment arrives at an ocean port, airport or the border. When the FDA data is filed for customs entry purposes, our clients are assured that every reasonable step has been taken to minimize the chance of delay or additional inquiries from either agency. In the event a delay occurs, the same compliance team will proactively work with you, the regional FDA office and your Livingston service team. Given our experience and close working relationship with various FDA offices, Livingston is often able to resolve such issues quickly and compliantly— often without any major impact to our clients’ pickup or delivery times.

Find out how Livingston can support your FDA import compliance efforts.



Livingston’s FDA Compliance Team provides a number of value added services including:

- Provide FDA product codes
- Research FDA regulations for your specific products
- Troubleshoot problem entries with the FDA
- On-call for Livingston’s teams at any time of day or night for FDA emergencies that may arise.
- Submitting requested information and/or documentation to the FDA
- Acting as a liaison between you and the FDA

Action equals results

The FDA recognizes Livingston International as a leading Phase 2, paperless filer with a high rate of demonstrated compliance. Livingston’s Phase 2, paperless status allows us to electronically submit information to and receive information from the FDA. Alternatively, Phase 1, paper filers are required to submit paper documents with every FDA shipment and wait for a paper based response from the FDA, which can significantly delay the release of your product to the market. Because Livingston is a Phase 2, paperless filer, our clients benefit from real time electronic updates on the FDA status of their shipments, improved product-cycle times and reduced warehouse requirements.



Benefits of working with Livingston's FDA team

We are proud of our FDA status and the resulting benefits we extend to you. Some of the key benefits in working with Livingston and our FDA Compliance Team include:

- Root cause analysis and resolution of FDA issues
- Product database review for compliance
- Dedicated and experienced resources for answering
- FDA related questions, researching and applying FDA regulations
- Webinars on important FDA regulatory changes
- Food facility designated agency services to help meet registration requirements under the Bioterrorism Act and the Food Safety Modernization Act

Next steps

Call today to learn how Livingston can support your FDA import compliance efforts. Please contact your Livingston representative or the FDA Compliance Team at 716-692-3100 (7018) or email fda@livingstonintl.com.

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Contact Livingston

Have questions or need help with your shipments? Contact your account executive, write to us at: simplify@livingstonintl.com or give us a call at **1-800-837-1063**

