When the Import Process Goes Sideways

Consumer goods such as cosmetics, wellness devices and drugs are subject to regulation by FDA, CBP, and other federal and state agencies. Learn what to do and what to avoid so your goods cross the border successfully.

All imported goods must meet the same standards as domestic goods. Imported drugs and devices must be safe and effective; cosmetics must be safe and made from approved ingredients; radiation-emitting devices must meet established standards; and all products must contain informative and truthful labeling in English.

FDA Registration and Listing

Many companies must register their facilities with FDA before they can import into the U.S. Additionally, cosmetic, drug and device companies which have registered must also must file documentation to list the products made at their establishments.

Classification of the Product

It is important to note that FDA and CBP may have different ways to describe and/or classify a product within their own agency terminology. Therefore, importers should work with their own supply chain to ensure that they are provided all the correct, supporting documentation for the shipment and the eventual presentation of the entry. It is important for the importer to work with its Customs broker in the United States to ensure that any description on the Customs entries and the actual Harmonized Tariff Classification comply with both FDA and CBP requirements.

Making Entry – U.S. Customs and Border Protection (CBP)

The import process begins with CBP, which works alongside the other partner federal agencies like FDA, USDA, EPA, USFWS, CPSC, DEA, and TTB to ensure those government agencies' legal requirements are met when products are attempted to be imported into the United States, and to enforce all relevant federal and state laws and regulations.

Download this free Importers Guide with practical tips and descriptions of key issues such as Country of Origin determination, classification considerations and Customs' ACE system.

After receiving the supporting documentation for the shipment and entry which are electronically filed through the CBP Automated Commercial Environment electronic system known as ACE, CBP redirects shipments of products such as cosmetics, medical devices, and drugs to FDA for further review. If a federal agent or the automatic system detect a possible issue with the supporting documentation and/or entry, then the federal agent will stop the attempted import at the port of entry, not permit the shipment to enter the United States

contact@fdaimports.com
(410) 220-2800

and examine the products. The potential examination may be a sampling of the shipment or an intensive examination of the entire shipment. If FDA finds anything that indicates a regulatory problem or deficiency, then a compliance officer will initiate the enforcement process.

Cosmetics

Numerous issues can trigger FDA scrutiny of a cosmetic shipment at the port of entry. The cosmetic label, advertising, and ingredients dictate how FDA will regulate a product. Claims that a product can prevent disease or that it will affect the structure or function of the human body are drug claims to FDA, even if the importer views the product as a cosmetic. Some common examples of impermissible drug claims include Cosmetic cellulite reduction claims, cosmetic skin whiteners, cosmetic wrinkle reducing products or sun protection cosmetic claims. The difference between permissible cosmetic claims and drug claims is often subtle and making the distinction requires expertise.

Additionally, FDA has created an Import Alert System that will automatically detain shipments from those companies that are on the alert list under the assumption that their shipments are in violation for a particular reason. For instance:

- Import Alert 53-06: Detention Without Physical Examination of Cosmetics Due to Color Additive Violations
- Import Alert 53-17: Detention Without Physical Examination of Cosmetics Due to Microbiological Contamination

Illegal color additives are a serious concern and compliance can be tricky since FDA has banned certain color additives that are legal in other countries. For this reason, cosmetic manufacturers may be surprised to find that their product contains a banned substance when it reaches a U.S. port of entry.

Medical Devices and Wellness Products

Medical devices encompass a variety of products from medical gloves to pacemakers. FDA assigns each medical device to one of three classifications, and each class of medical device requires different controls. For example, most of the Class II devices must demonstrate to FDA that the device is “substantially equivalent” to a product already on the market. This is done by submitting data in the form of a 510(k) filing. A Class III device, on the other hand, must undergo Pre-Market Approval (PMA) through FDA, a more exacting process. If FDA discovers that an imported device lacks a 510(k) or a PMA, FDA will hold the product at the port. In addition, FDA will list the company on an Import Alert and all future shipments will be detained as well.

Even for commonplace Class I devices like sunglasses and gloves, FDA has issued performance standards. For sunglasses, FDA requires a certain level of impact resistance to decrease potential injury to the eyes. When a shipment of sunglasses reaches a U.S. port, FDA may examine the incoming shipment for resistance to impact, and if FDA finds that the lenses break at a rate that exceeds the standard, they will detain the shipment.

Related import alerts:

- Import Alert 89-08: Detention Without Physical Examination of Devices Without Approved PMAs or IDEs and Other Devices not Substantially Equivalent or Without a 510(k).

- Import Alert 86-07: Detention Without Physical Examination of and Guidance for Impact-Resistant Lenses in Eyeglasses and Sunglasses.

The import process is further complicated by the trend in the market to make products to promote general wellness of the body using novel marketing claims or tools. (See article on wellness products.) These products often blur the line between medical devices and consumer products. Despite the manufacturer's intent to market the device as a consumer product, an FDA port officer may find the product in violation of a medical device regulation due to marketing claims. Once again, the advice of an expert on these matters could prove invaluable to a manufacturer or importer.

Homeopathic Drugs

In recent years, the homeopathic drug industry has experienced rapid growth, and as sales of homeopathic drugs have increased, so have FDA enforcement actions against homeopathic drug manufacturers. The difficulty is that the regulations for homeopathic drugs differ from those that govern traditional medicines, and manufacturers are often unfamiliar with the differences.

Since homeopathic drug manufacturers usually market their products as over-the-counter (OTC) drugs, aggressive drug claims can lead FDA to consider them mislabeled prescription drugs. For example, if the marketing of a homeopathic drug implies that it treats a disease that requires a physician, FDA will likely deem it a prescription drug and hold the shipment.

IF A SHIPMENT IS DETAINED AT THE PORT, ACT QUICKLY TO GET YOUR PRODUCT RELEASED.

FDA may stop the importation of OTC drugs for reasons as complicated as the interrelation between the active ingredients and permissible marketing claims or for reasons as simple as the improper declaration of the foreign manufacturer's address.

This last point highlights how vital it is, regardless of the type of good you are importing, to accurately transfer information from manufacturing facility to trading company/agent to shipper to the importer's Customs Broker who electronically files the information with CBP through ACE. FDA can detain a properly formulated and labeled product due to gaps or inconsistencies in the shipment information. If just one word of the foreign manufacturer's address differs from the registered address, the CBP ACE system will flag it as an unregistered facility, and FDA will put a hold on the shipment.

When a shipment is detained at the port, it is imperative that the manufacturer/importer locate and correct the problem before costs mount. Held shipments can mean unexpected warehouse fees, delays in customer delivery resulting in loss of money for retailers and distributors, and ultimately damage to the brand.

The regulatory consultants and affiliated attorneys at FDAImports.com help when goods are detained, but just as important is the pre-market work we do to help companies be better prepared before they import. Contact us today to learn more.