

What FDA detains and why? And how you can avoid import refusals

The US Food and Drug Administration (FDA) may detain regulated products that appear to be out of compliance with FDA regulations. For imported products, FDA may refuse entry, and the refused product must be destroyed or re-exported. Refusals are costly to exporters and importers. They are not entirely unpredictable, however. Indian manufacturers and exporters can reduce their exposure just by avoiding common causes of FDA action.

To assist Indian manufacturers and exporters, Registrar Corp has compiled the following statistics concerning FDA import refusals. Registrar Corp analysts reviewed published information for each import detention reported by FDA during a three month sample period from May through July, 2009.

The data suggest obvious checks any savvy manufacturer and exporter should make prior to shipping. Most FDA detentions result not from problems with the product itself, but because the manufacturer or exporter

simply failed to confirm compliance with FDA regulations before shipping.

The most common reason for FDA detention was failure to label the product correctly, either by failing to follow FDA rules for the particular product or by labelling which caused the FDA to “deem” the product “an unapproved new drug” where a properly labelled product would not have been so deemed. Together, these two grounds comprise 43.7% of FDA detentions.

Most of these detentions could have been avoided by pre-shipment label review. Foods, dietary supplements, cosmetics and drugs all landed in the “unapproved new drug” category because of the product label, which often could have been corrected if the company had known of the problem before shipping. Other products simply failed to follow the particular labelling rules prescribed by the FDA for the specific product or more general labelling restrictions applicable to all FDA regulated products.

FDA’s inspection is random; products which may have gained entry on previous occasions notwithstanding the erroneous label were nevertheless subject to refusal on subsequent imports.

Almost 20% of FDA detentions were for failure to make required electronic filings. Drug and medical device companies suffered from fail-

ures to register their establishments and properly list all devices and drugs. Food manufacturers faced similar problems from failures to register their establishments with FDA’s Low Acid Canned Food (LACF) Unit or to file scheduled processes (SIDs) for low acid or acidified foods. Again, these were generally avoidable, but failure to check in advance caused loss of money, time and caused the destruction of valuable merchandise.

Avoidable FDA Refusals Affected Even Knowledgeable Companies From Countries with Similar (but different) Regulations.

FDA-regulated companies suffered detentions from improper labelling even where a country’s own labelling regulations are similar to those of FDA, such as in the European Union or Canada. Many companies mistakenly assumed that FDA’s labeling rules are identical to the European Union or Canada — and then discover that a detail in United States regulations is different.

Similarly, food manufacturers from countries reputed for gourmet delicacies often suffer from FDA detentions because they have not filed required registrations and process filings with FDA’s LACF Unit. Valuable gourmet products prized everywhere were destroyed or returned at great cost by failure to file appropriate documentation in advance. ■



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