You Can Check Out Anytime You Want, But You Can Never Leave: FDA Import Detentions and Recommendations to Minimize Delays

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In The Eagles' song, "Hotel California," Don Henley sings, "You can check out anytime you want, but you can never leave." Life science companies can try to import all they want, but that doesn't mean the products will make it into the United States.

It seems lately that the Food and Drug Administration has been detaining client products – actually, we were retained after the import detentions were imposed -- more frequently. While we do not have any empirical evidence to suggest there is an agency-wide increase in such holds, we thought we'd provide a short overview of FDA's enforcement authority in the area and offer some recommendations to minimize delays. These delays can cause the loss of thousands, if not millions, of dollars.

We will only focus on FDA issues; other government agencies might be involved in product entry. We will also not discuss here the FDA import detention process or the reimportation statutory provisions in detail.

FDA's Authority

- The Federal Food, Drug, and Cosmetic Act gives FDA the authority to detain products if they "appear" to be violative. The "appears" language offers the agency wide latitude to stop entry and ask questions later.
- FDA may sample the product (at the District level) and either allow the product to proceed or require its destruction or export, if it concludes entry should not be allowed (we will not discuss here FDA's import for export statutory provisions).
- A hold can take days, if not weeks, particularly if the matter is referred to FDA headquarters. Recently, a district office held a client's products for two weeks, before asking the Center for Devices and Radiological Health to review the products' regulatory status. CDRH took only a few days, but the complete hold took close to three weeks to resolve, causing hundreds of thousands in lost sales.
- FDA may want to physically witness the destruction or re-exportation of the product, on the company's dime.

Common Reasons for Import Detentions

While there is not an exhaustive list of reasons why FDA, with the U.S. Customs and Border Protection, might detain products, such as pharmaceuticals or medical devices, we see certain common problems.

On the technical side

- manufacturer or initial importer not registered with FDA
- product not listed with FDA
- product not approved or cleared in the U.S.
- labeling deficiency
- for medical devices, the product is not covered by a 510k or PMA
- label not in English
- no U.S. agent for foreign firm

On the substantive side

- country of origin - - some countries' lack of quality-related systems, which are not similar to the U.S., often causes scrutiny
- label is false or misleading
- undeclared active ingredients or unauthorized health claims
- type of product imported might be susceptible to more scrutiny (e.g., cosmetic label makes drug-like claim)
- some ports seem to be more difficult due to logistical and security reasons

AGG Recommendations to Minimize or Mitigate Delay

- If the government wants to detain products, it will do so, and there's little a company can do to prevent this. However, here are some recommendations to minimize such risks
- Know the above rules and, when in doubt, check with FDA or seek outside assistance
- Establish a product safety management program that defines the responsibilities of each individual in the importing process and adhere to that program with diligence
- Make sure the technical and administrative matters (e.g., forms and label) are accurate
- Make sure your importer knows the rules, and has complete information about the manufacturer in documentation before shipment
- Know the regulatory status of your product
    - one "new" product can change the regulatory scrutiny of the products
- Make sure foreign facility making/shipping product has good compliance record
- Know the details of your product (e.g. product composition, specifications, safety concerns, packaging) and become familiar with the regulatory requirements that apply
- When possible, establish mechanisms with foreign facility to ensure compliance, and consider working with firms certified by the U.S. government

To paraphrase The Eagles, if you want to check in, you want to make sure you can leave (to sell your product).

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