Imported Products- FDA Is Not Fooling Around

by John R. Fleder

FDA issued a sweeping Import Alert detaining, without physical examination, milk products, milk-derived products, and food products containing milk from China, on November 12, 2008, in response to concerns over melamine contamination of China's milk products.[1] Although it lists "product codes" that might be used by an importer to describe these types of foods, in reality, any food identified with one of these product codes will be detained, regardless of whether it actually contains milk.

This Import Alert is yet another recent example of FDA's enhanced enforcement efforts regarding all imported products within FDA's jurisdiction. The Federal Food, Drug, and Cosmetic Act ("FDC Act") has long given FDA broad authority over imports. Faced with increased pressure from Congress, the media and the consuming public, FDA appears to be dramatically stepping up its authority over imported products.

Background

The FDC Act prohibits the introduction or delivery into "interstate commerce" of any violative product.[2] The term "interstate commerce" means, in relevant part, "commerce between any State or Territory or any place outside thereof."[3] All FDA-regulated products are subject to examination by FDA when they are offered for import into the United States. All imported products are required to meet the same standards as domestic goods.[4] For example, drug products must be safe and effective for their intended use(s), most of them must be covered by an investigational new drug application (IND) or a new drug approval (NDA), and they must be manufactured according to good manufacturing procedures (GMPs).

FDA, in conjunction with the U.S. Customs and Border Protection (CBP), a component of the Department of Homeland Security, is authorized to examine every product offered for import that is subject to FDA's jurisdiction. FDA uses the "Operational and Administrative System for Import Support" (OASIS) to review coded entries offered for import. While FDA reviews information contained in OASIS, the importer must hold the entry and not distribute it into domestic commerce until it is released by FDA through a "may proceed" notice. FDA may determine that the entry must be "detained," requiring the importer to provide further documentation, within a specified time period, confirming the compliance of the products. If the time period elapses without an importer response, or if the importer's response is inadequate, FDA can "refuse" the entry. FDA will forward the refusal information to CBP, which typically will request redelivery (for exportation or destruction of the products) within 90 days. If redelivery is not accomplished, CBP may seek liquidated damages from the importer of three times the value of the product.

The number of FDA import lines[5] has increased dramatically in the last decade. In FY 1997, there were less than 5 million FDA import lines brought into the United States.[6] By FY 2007, that number was 15.9 million lines with 17 million lines estimated for FY 2008.[7] Since 2001, the number of drug products manufactured at foreign sites has more than doubled.[8] Given the increased globalization of FDA-regulated goods sought to be marketed in the United States, it is not surprising that FDA might be overwhelmed. However, its inconsistent enforcement creates further challenges.

Inconsistent Enforcement

The FDC Act provides that FDA may refuse admission to an article that "appears from the examination of such samples or otherwise" to be violative.[9] Because of the subjective nature of the terms "appears" and "or otherwise," the regulation of FDA-related imports is often inconsistent around the country. Recently, at a conference on imports held by FDLI, Domenic Veneziano, FDA's Director of the Division of Import Operations and Policy,

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acknowledged that the agency was operating under an out-of-date system for handling imports.10 He recognized the challenges posed by antiquated systems, integration issues between multiple sources of data, the lack of validation and screening capability for such a large quantity of imported products, and the presence of duplicative records within these systems.

The wording of the FDC Act is partially responsible for these inconsistencies. Under section 801, FDA may refuse any product that may "appear" to be violative based on its examination of the product.

The authors' firm has been involved in numerous import matters that demonstrate inconsistent enforcement actions by FDA. For example, it has become generally accepted that the New York District Office is very active in scrutinizing and detaining prescription drug imports that may have been released by other offices. Further, the Los Angeles District Office is known for closely examining dietary supplement products. There are even inconsistencies in enforcement within a district, from reviewer to reviewer. Some reviewers have taken it upon themselves to conduct web searches to determine how products proposed for entry may be marketed. There have been times when importers have been subject to product detentions, not based on the way the importer markets the product, but based on the way a third party may be doing so. Although these situations may often be resolved with the product's eventual release, these detentions result in costly delays for the importer, oftentimes through no fault of its own.

The wording of the FDC Act is partially responsible for these inconsistencies. Under section 801, FDA may refuse any product that may "appear" to be violative based on its examination of the product. In other words, there need not be an actual adulteration or misbranding violation under the FDC Act, but rather the mere appearance of a violation. Further, the term "or otherwise" arguably allows FDA import officials to consider not only an examination of samples, but also the prior history of the product, foreign manufacturer, exporter, importer, consignee, geographic region or country. Because this information is frequently not kept in a centralized location at FDA headquarters, FDA District Offices and their individual reviewers are left to make subjective determinations about the status of a proposed entry.

Importers have had products detained for many reasons other than the importer's act of causing potential safety and labeling issues with regard to the products themselves. Detentions have also been based on how third parties promote the products, a history of misdeeds on the part of the consignee or a minor paperwork error where a correction is unacceptable to a reviewer because of the importer's history of minor paperwork errors. These subjective determinations often lead to lengthy and potentially costly delays that in turn lead to "port shopping," whereby an importer chooses to bring an entry into a port that is not known for scrutinizing particular types of regulated products.

Import Alerts

Based in part on the inconsistencies in enforcement, FDA established nationwide Import Alert Procedures in the early 1970's, although prior to that time "import circulars" were disseminated to FDA District Offices.11 According to Mr. Veneziano, the first "Import Alert" was issued in 1974. The purpose of an Import Alert is to identify and disseminate import information (problems, violative trends, etc.) to FDA personnel throughout the country, thus providing for more uniform and effective import coverage. Import Alerts identify problem commodities and/or shippers/manufacturers and provide guidance for import coverage. FDA has recognized these products or shippers/manufacturers as having met the criteria for Detention Without Physical Examination – meaning that that these entries will be stopped without examination. The burden is then placed on the importer to prove the product is not violative and thus overcome the detention before FDA issues a "Refusal" for the import. Where the Import Alert is based on prior violative shipments, FDA will typically require a certain number of consecutive non-violative shipments before removing the shipper/product from the Import Alert list.

Import Alerts typically have been narrowly drawn to include specific products and/or shippers. Recently, however, FDA has utilized very broad Import Alerts as a means to increase border

protections. In 2007, FDA issued an Import Alert on bulk vegetable proteins from China based on suspected melamine contamination before FDA had established acceptable testing standards for melamine.12 For several weeks thereafter, compliant products were subjected to what many people believed were unnecessary import delays. Without appropriate testing standards in place, importers were left with no means of providing adequate information to FDA to secure the product's release from CBP.

In the recent Import Alert on Chinese milk products, foods that do not contain milk products but are imported using a product code listed in the Import Alert also are likely to be detained (e.g., cereal preparations, snack foods, and candy specialties). These stop-gap measures require an extraordinary amount of importer resources to overcome barriers to compliant products entering the United States.

The good news is that FDA is aware of the inadequacies in its systems and is working to correct them.13 Between efforts to modernize and integrate their computer systems to the creation of more formalized import dispute resolution procedures, FDA is striving for more consistent enforcement. It remains unclear, however, how quickly FDA will be able to implement these changes. In the meantime, importers will continue to face major hurdles in getting their FDA-regulated products into the U.S.

Dara Katcher Levy, an associate at Hyman, Phelps & McNamara, assisted in writing this article.

1 Import Alert #99-30, "Detention Without Physical Examination of All Milk Products, Milk Derived Ingredients and Finished Food Products Containing Milk from China Due to the Presence of Melamine and/or Melamine Analogs," November 12, 2008. *Available at* http://www.fda.gov/ora/fiars/ora_imports_ia9930.html.
2 FDC Act § 301(a).
3 Id. § 201(b) (emphasis added).
4 Although all products imported for domestic commerce must meet the same standards as domestic goods, violative imports identified as "import for export" may be permitted entry.
5 An import line is a particular product line within an imported entry. An entry may contain multiple types of FDA regulated products. Each product type would be assigned its own line number.
6 John Verbeten, Presentation to: Food and Drug Law Institute, Address before the Food and Drug Law Institute (October 24, 2008).
7 Id.
8 Deborah M. Autor, Globalization: Challenges and Recent Case Studies, Address before the Food and Drug Law Institute (October 24, 2008).
9 FDC Act § 801(a) (emphasis added).
10 Domenic Veneziano, FDA Facing Imported Challenges of Today and Tomorrow, Address before the Food and Drug Law Institute (October 24, 2008).
11 Regulatory Procedures Manual, Ch. 9-13, "Import Information Directives," (March 2008). *Available at* http://www.fda.gov/ora/compliance_ref/rpm/chapter9/ch9-13.html.
12 Katia Fowler, Costs Mount for Firms as Amino Acids, Vegetable Proteins Sit on Docks, [THE PINK SHEET DAILY] (May 16, 2007).
13 Id. at 10.