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US FDA Authority over Imports

Linda Horton explains the tools the Food and Drug Administration uses to deal with "violative" products entering the US.

In recent years, the US Food and Drug Administration has faced increasing challenges in overseeing the safety of agency-regulated products generally, and particularly imported pharmaceutical products from developing countries. The agency carries out several hundred inspections each year of foreign pharmaceutical establishments that ship products to the US. The number inspected each year, however, is only a small fraction of the total.

The FDA inspects only a small fraction of the foreign pharmaceutical establishments that ship products to the US

In the wake of some high-profile safety scares – most notably, the importation into the US of contaminated heparin from China that was associated with serious patient injuries and deaths – the FDA has launched a number of projects to monitor drugs before they reach the US. For example, the agency has opened new offices in China, India, Latin America and Europe under the Beyond Our Borders initiative[1] and is in the process of setting up a voluntary secure supply chain pilot programme[2].

Though the agency is increasing its overseas presence, most of the FDA's import-related activities take place in the US. The Federal Food, Drug, and Cosmetic Act prohibits the importation of unapproved new drugs, ie any drugs, including foreign-made versions of FDA-approved drugs, that have not received FDA approval to demonstrate they meet the federal requirements for safety and effectiveness[3]. The FDA, in collaboration with US Customs and Border Protection (Customs), is responsible for enforcing this. This article provides a primer on the agency's authority in this area.

Import procedures

Section 801 of the FDCA prescribes the procedure for drugs, devices, food and cosmetics imported or offered for import into the US. The act stipulates that an article shall be refused admission "[i]f it appears from the examination of such samples or otherwise" that it[4]:

- has been manufactured, processed or packed under unsanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device, do not conform to the FDA's good manufacturing practice regulations;
- is forbidden or restricted in sale in the country in which it was produced or from which it is being exported; or
- is adulterated, misbranded or in violation of the act's new drug provisions.

The FDA and Customs screen entry documents, either electronically or manually, at nearly a 100% level, to determine the degree of regulatory interest in the shipment based on compliance history, policies, priorities and information from various sources. Approximately 3-4% of entries are sampled, and approximately 3-4% of entries are wharf-examined (products that are physically examined upon arrival). The FDA targets high-risk products or products with high violation rates, and determines what action to take regarding the entry. For example, the agency may decide to conduct a wharf examination, sample the product or permit the product to proceed without agency review[5].

The agency targets high-risk products or those with high violation rates

The FDA has authority to detain imports that "appear" to be adulterated or misbranded but lacks identical detention authority for domestically produced goods that "appear" to be adulterated or misbranded. This disparity opens the door to a charge that the additional authority given to the FDA to regulate imports is at odds with the World Trade Organization's national treatment principle, which says that imported and locally produced goods should be treated equally – at least after the foreign goods have entered the market[6].

On the other hand, it can be argued that the FDA's power to intercept "apparently" violative imports merely reflects the comparatively greater difficulty in ascertaining whether imported products, and the conditions of manufacture that influence product quality, meet requirements.

Detention without physical examination

Detention without physical examination is an FDA programme that was developed to deal with recurrent violations. It involves the detention of an entry of a specified article, solely on the basis of information regarding the past violative history of that producer – or, more controversially, that country – or other information indicating that the product may be violative. The FDA developed this programme, formerly known as "automatic detention," based upon its statutory authority to refuse admission of any product that "appears" from examination "or otherwise" to be violative. The agency cites past history of violative shipments as justification to predict all future shipments of such products from the same source "appear" violative and, therefore, subject to detention without physical examination, unless and until the importer or foreign producer demonstrates compliance.

Detention without physical examination was developed to deal with recurrent violations

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To implement a detention without physical examination, FDA headquarters issues to its investigators and to Customs an import alert stating that all shipments of a certain product or class of products from a certain supplier, or from a certain country, are subject to detention without physical examination. In some cases, goods subject to detention without physical examination may be permitted into the US only if the importer produces a certificate from the foreign government, or an acceptable private laboratory test result that the FDA accepts as assurance that the product is in compliance with the requirements of the FDCA.

The FDA may accept certificates or lab results where a violation involved an impermissible contaminant

Certificates or laboratory test results often are accepted by the FDA in cases where the violation involved an impermissible contaminant such as pesticide residues, and the agency may conduct audits or spot checks of "certified" shipments to ensure that the products covered by the certificates comply with the law. In other cases, test results do not satisfy the agency's need for assurance that the problem was remedied (eg such problems as underprocessed canned foods, most drug GMP violations and GMP problems with defective steel surgical devices). Detention without physical examination amounts to a lot-by-lot release programme in which the importer must prove the eligibility of the product to be sold in the US.

Actions against imports

FDA actions on imports are implemented through FDA documents known as Import Alerts. Import Alerts, including detention without physical examination, are public and are available on the agency's website[7]. Thus, foreign countries, exporters and importers can easily learn about which products have been detained and why.

If the FDA determines that an entry appears violative, it may refuse entry of the article unless it can be brought into compliance with the FDCA. If the article cannot be brought into compliance, it must be re-exported or destroyed[8]. The owner or consignee "may appear before the [FDA] and have the right to introduce testimony". This proceeding is referred to as a hearing in FDA regulations[9]. This is not a full-blown, trial-type administrative hearing. The importer can introduce testimony orally or in writing. FDA officials do not offer evidence, but listen to the importer's presentation. It is an opportunity for the importer to try to convince the FDA that its proposed action concerning the shipment is in error. There is no cross-examination, and often no recording or transcript made of the proceeding.

An importer may be allowed to try to bring the illegal product into compliance through reconditioning

As an alternative to re-exportation or destruction, an importer may be permitted by the FDA to try to bring the illegal product into compliance with the law through reconditioning, before a final decision is made as to whether it may be admitted. Conditional release of a product for reconditioning is regarded as a privilege rather than a right, and repetitious shipments of the same illegal product may result in detention without physical examination and re-exportation. (It should be noted that, other than easily corrected label violations, reconditioning is less likely to be an option for imported drugs and medical devices than for foods.)

The option of seizure and destruction is available. Section 801 of the FDCA appears to give the importer of a violative product the option to re-export (or recondition) – rather than destroy – a product offered for importation that does not comply. Section 304 of the FDCA, the source of the FDA's seizure authority, provides another option. The FDA can admit an imported product into interstate commerce, and then seize it and seek its destruction via a district court order. Once the district court orders destruction of the seized product, the importer is not entitled to re-export a product considered dangerous by the FDA[10,11].

Conclusion

The FDA's efforts focus on dealing with problems at the source, before they are passed on to the US

With the renewed attention to import safety, the FDA is intensifying its efforts to work with developing countries that have had a large number of entries detained. The objective of such efforts is to identify and deal with a problem at the source, before it is passed on to the US. The fact that many US imports originate in developing countries that do not in all cases have strong regulatory systems contributes to the import safety challenge faced by the FDA and other regulators[12]. Thus, the FDA continues to rely on its authority on US soil in addition to its overseas efforts.

References

1. *The Regulatory Affairs Journal – Pharma*, 2009, **20**(2), 126
2. *Federal Register*, 15 January 2009, **74**(10), 2605-2608, www.fda.gov/OHRMS/DOCKETS/98fr/E9-791.pdf
3. FDCA, Chapter VIII, Imports and Exports, 21 USC 381, www.fda.gov/opacom/laws/fdcact/fdcact8.htm
4. See Reference 3, subsection 381(a)
5. 21 Code of Federal Regulations, subsection 1.90
6. WTO, Principles of the trading system, www.wto.org/english/theWTO_e/whatis_e/tif_e/fact2_e.htm
7. FDA, Import Alerts, www.fda.gov/ora/fiars/ora_import_alerts.html
8. See Reference 4
9. 21 Code of Federal Regulations, subsection 1.94(a)
10. 64 F.3d 984 (5th Cir 1995)
11. 64 F.3d at 992
12. Horton LR, Food from Developing Countries: Steps to Improve Compliance, 53 Food Drug Cosm. L.J. 139 (1998)

