Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

FDA Ups Ante On Drug Inspections With Detention Authority

Law360, New York (June 23, 2014, 12:22 PM ET) -- New authority allows inspectors from the U.S. Food and Drug Administration to quickly detain products during inspections if they believe the products are misbranded or adulterated.

The FDA has long sought increased enforcement mechanisms to add to its enforcement capabilities. As early as the 1990s, FDA expressed its desire for "... administrative detention authority on all products regulated by [the FDA]" in order to stop the movement of potentially violative products "in emergency situations."[1] Traditionally, the Federal Food, Drug, & Cosmetic Act required FDA to use in rem seizure actions to remove unsafe or impure products, including drugs, from the market. Seizure actions require significant time and FDA resources. The ability to administratively detain many FDA-regulated products, including medical devices, tobacco and food, was previously granted by Congress to the agency under various amendments to the FDCA. However, despite legislative attempts by late Sen. Ted Kennedy and others in 2009 to expand detention authority to drugs, it was not granted until the passage of the Food and Drug Administration Safety and Innovation Act of 2012. FDASIA required the FDA to promulgate regulations concerning this new detention authority.

With the stated goal of "better protect[ing] the integrity of the drug supply chain," on May 29, 2014, the FDA issued a final rule outlining the procedure it will follow during inspections in administratively detaining drugs believed to be misbranded or adulterated.[2] The rule, which takes effect on June 30, 2014, amends 21 C.F.R. parts 1 and 16 to extend the authority that the FDA already has over medical devices and tobacco products to include human and animal drugs. This new authority may significantly impact the tenor and process of inspections and may make inspection readiness more important than ever for drug manufacturers.

Overview of the New Rule

The new enforcement tool permits inspectors, described as "authorized FDA officials," who are conducting inspections to detain drugs when the official has "reason to believe" the drugs are

"adulterated or misbranded." The rule describes the procedures, including detention periods and an appeal process, for drugs that may be subject to this new enforcement tool.

When an inspector "has reason to believe" that a drug is adulterated or misbranded, the new regulation authorizes an administrative detention[3] not to exceed 20 calendar days. The relevant district director may extend the period a further 10 calendar days if it is determined that a greater period of time is required to seize the drugs, to institute injunction proceedings, or to evaluate the need for legal action.[4]

The relevant district director must approve a detention order before it can be issued by an inspector.[5] Further, the detention order must be written and signed by the inspector and sent to the owner or user of the drugs; the owner, operator or agent of the facility where the drugs are located; and the shipper of record (if applicable).[6] The order must identify the drugs and the reason for their detention, among other administrative items.[7]

The regulation provides for an appeal to the regional director, which must be submitted in writing to the district director within five business days after receiving a detention order.[8] If a request for an informal hearing by the owner/agent is included with the appeal, the hearing must either be held within five business days after filing the appeal or at a later agreed-on date no more than 20 calendar days after receiving the detention order. On appeal, the presiding FDA officer must hold the hearing and render a decision that affirms or revokes the detention within five working days. Per normal FDA procedures, these informal hearings can be brief and are often held by telephone.

Until the detention order is removed through the appeal process, is terminated, or expires, movement of the drugs is limited to keeping them out of the way of the establishment's operation, destroying them, bringing them into compliance or other movement for a purpose deemed necessary by the FDA.[9]

If the detention is terminated or expires, the district director must issue a termination notice to the person who received the detention order.[10] During the detention period, and for two years after, specified records must be kept regarding the manufacturing, processing and distribution or other movement of the drugs, unless a shorter time is permitted by the FDA.[11]

Administrative detention does not prevent the FDA from taking additional legal action against the drugs, including seizure or a request that the drugs be destroyed or brought into compliance with the Act.[12]

Impact on Drug Manufacturers

Although the FDA has been historically reluctant to use administrative detention as an enforcement tool in the device and food industries, it is uncertain if it will exercise the same restraint in connection with drug products, which can present more immediate adverse health threats to the public. Consistent with the broad statutory definitions of "misbranding" and "adulteration" in Sections 501 and 502 of the Act, the FDA's regulation gives broad powers to the inspector, who merely needs to "believe" that the drugs

"may" be in violation to support their detention. Therefore, the criteria used to identify a product to be detained is likely to be highly variable and fact specific.

The possible implications of FDA's use of this new authority include the following:

- an increased adversarial tone to inspections and potentially more extensive sampling during inspections;

- potentially prolonged inspections when detention orders are being negotiated internally at the FDA and/or more intense leverage by the agency for companies to voluntarily agree to quarantine a product or face a detention order;

- the potential for uneven use of detention authority across district offices and inconsistent views interpreting "adulterated and misbranded;"

- a possible impact on supply contract provisions, including notice of the detained product to customers;

- a need to revise company inspection standard operating procedures to account for detention order negotiation and process, including appeals (e.g., notice within the company, assignment of responsibility for handling detentions and decisions whether to appeal, and identification of secure areas for physical separation of the detained product, whether voluntarily or under a detention order); and

- additional training and inspection readiness audits, including new processes for detentions.

—By Kathleen M. Sanzo, Ann M. Begley, Rebecca L. Dandeker and Mark C. Bolin, Morgan Lewis & Bockius LLP

Kathleen Sanzo, Ann Begley and Rebecca Dandeker are partners and Mark Bolin is an associate in Morgan Lewis & Bockius' Washington, D.C., office. Sanzo is the leader of the firm's FDA practice group.

[1] FDA Authority to Pursue Civil Monetary Penalties Against FD&C Act Violators Recommended By Chief

Counsel Porter; Agency Would Like Power to Order Recalls, The Pink Sheet, Dec. 24, 1990, at 12-13 (quoting testimony of FDA's Office of Regulatory Affair's Enforcement Director Alan Hoeting).

[2] Administrative Detention of Drugs Intended for Human or Animal Use, 79 Fed. Reg. 30,716 (May 29, 2014) (to be codified at 21 C.F.R. pts. 1 and 16), available at http://www.gpo.gov/fdsys/pkg/FR-2014-05-29/pdf/2014-12458.pdf. The rule implements amendments to Section 304(g) of the Federal Food, Drug, and Cosmetic Act under Section 709 of the Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144 (July 9, 2012).

[3] 21 C.F.R. § 1.980(b).

[4] 21 C.F.R. § 1.980(c).

[5] 21 C.F.R. § 1.980(e). An oral order must be drafted in writing as soon as possible.

[6] 21 C.F.R. § 1.980(d).

[7] 21 C.F.R. § 1.980(d)(3)(i)-(xi).

[8] 21 C.F.R. § 1.980(g)(1).

[9] 21 C.F.R. § 1.980(h)(3). Detained active pharmaceutical ingredients may be incorporated into finished forms, but then sequestered pending the appeal. 21 C.F.R. § 1.980(h)(2).

[10] 21 C.F.R. § 1.980(j).

[11] 21 C.F.R. § 1.980(k).

[12] 21 C.F.R. § 1.980(i).