

## life sciences and healthcare lawflash

from the FDA Practice

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### FDA Ups the Ante on Inspections with New Administrative Detention Authority

*New authority allows FDA inspectors to quickly detain products during inspections if they believe the products are misbranded or adulterated.*

The U.S. Food and Drug Administration (FDA) has issued a final rule<sup>1</sup> that authorizes FDA to administratively detain drugs during inspections if the drugs are believed to be misbranded or adulterated. The rule, which takes effect on June 30, 2014, amends 21 C.F.R. parts 1 and 16 to extend the authority that 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—which is intended to better protect the integrity of the drug supply chain—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<sup>2</sup> 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.<sup>3</sup>

The relevant district director must approve a detention order before it can be issued by an inspector.<sup>4</sup> 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).<sup>5</sup> The order must identify the drugs and the reason for their detention, among other administrative items.<sup>6</sup>

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. 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

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1. 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 (the Act) under section 709 of the Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144 (July 9, 2012).

2. 21 C.F.R. § 1.980(b).

3. 21 C.F.R. § 1.980(c).

4. 21 C.F.R. § 1.980(e). An oral order must be drafted in writing as soon as possible.

5. 21 C.F.R. § 1.980(d).

6. 21 C.F.R. § 1.980(d)(3)(i)-(xi).

appeal or at a later agreed-on date no more than 20 calendar days after receiving the detention order.<sup>7</sup> 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 FDA.<sup>8</sup>

If the detention is terminated or expires, the district director must issue a termination notice to the person who received the detention order.<sup>9</sup> 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 FDA.<sup>10</sup>

Administrative detention does not prevent 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.<sup>11</sup>

## Impact on Drug Manufacturers

Although 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, 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 FDA and/or more intense leverage by FDA 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)
- Additional training and inspection readiness audits, including new processes for detentions

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7. 21 C.F.R. § 1.980(g)(1).

8. 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).

9. 21 C.F.R. § 1.980(j).

10. 21 C.F.R. § 1.980(k).

11. 21 C.F.R. § 1.980(i).

# Morgan Lewis

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