Spelling Counts (Among Other Things): FDA Issues Warning Letters for Mistakes in Drug Listing

Deborah L. Livornese and Alan G. Minsk

Background

Recently, the Food and Drug Administration issued two Warning Letters to pharmaceutical companies for failing to fulfill product listing obligations for what appear to be oversights. In the first letter issued at the end of April, FDA said the lists of active ingredients in the product listing and in the product labeling did not match.[1] The listing included an active ingredient not found in the product labeling, and the product labeling contained an active ingredient not found in the listing. The agency also noted and requested correction of a spelling error in one of the ingredients. In the second letter, issued June 1, FDA again found a discrepancy between the active ingredients in a product label and in the listing information.[2]

In each case, the agency said that the failure to fulfill the listing obligation rendered the product misbranded. In addition to sending out the Warning Letters, FDA removed each product's listing information from the National Drug Code (NDC) directory made available to the public until the corrections are made. In removing the listings from the NDC directory, FDA stated, in each letter, that it did so in an "effort to protect and promote the public health."

AGG Observations

- We don't know why FDA looked at the listings for these particular products carefully, but what appear to be relatively minor mistakes resulted in not only issuance of a Warning Letter, but also in removal from public access of what may be an important source for confirming NDC numbers.
- In some companies, listing is sometimes treated as a literal check the box task, but it must to be done carefully and by soeone who will compare the list of ingredients to the correct label and will also catch spelling mistakes. The misspelling wasn't for a particularly esoteric ingredient – "sulfer," which might have been a particular concern to the FDA.
- While, in these cases, FDA issued Warning Letters, the agency could also issue an Import Alert for a similar violation to prevent violative products from entering the United States. This can result in significant shipment delays and financial losses. Fixing even minor technical errors can take weeks, if not months.
- Of note, although the product that was the subject of the April letter is an unapproved prescription drug, the Warning Letter did not take issue with or refer to the drug's regulatory status.
- Typically, we see FDA taking action for much more substantial issues, such as quality-related issues or unapproved products. However, laws are laws, and noncompliance is noncompliance. Therefore, companies must remain vigilant and deliberate when ensuring compliance with, perhaps, even more ordinary and mundane requirements.

1 The April Warning Letter may be accessed at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm554253.htm

2 The June Warning Letter may be accessed at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm561702.htm

Authors and Contributors

Deborah L. Livornese
Partner, DC Office
202.677.4922
deborah.livornese@agg.com

Alan G. Minsk
Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

not *if*, but *how*.®

About Arnall Golden Gregory LLP

Arnall Golden Gregory, a law firm with more than 150 attorneys in Atlanta and Washington, DC, employs a "business sensibility" approach, developing a deep understanding of each client's industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal's prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief "not if, but how.®" Visit www.agg.com.

Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: **http://www.agg.com/subscribe/**