Who Me? Yes, You. Couldn't Be. Then Who?: FDA Reinforces That Contract Manufacturers Can't Delegate Away Regulatory Responsibilities

Alan G. Minsk

On When my children were younger, we played a little game about "who took the cookie from the cookie jar" – Who me? Yes, you. Couldn't be. Then who? We'd turn to another family member and start the game all over again. (Apparently, this dates back to my wife's childhood.) This memory came to mind when reviewing a Warning Letter, recently issued by the Food and Drug Administration, to a Chinese contract drug manufacturer.[1] FDA reiterated that the company could not delegate away its regulatory obligations or point to others for compliance.

Highlights

While the Warning Letter cited the drug company for a number of current Good Manufacturing Practice deficiencies, we will highlight some of the observations we thought of particular interest.

- The company was a contract manufacturer of over-the-counter drug products marketed to children. The company, however, released the products "without data to support their conformance to specifications, including identity and strength."
- The contract manufacturer company responded that its customers may do the testing after product lot releases. Nevertheless, it also noted that it "will arrange to have … finished drug product tested for identity and strength by an external laboratory once a year."
- The company did not include a testing requirement of each lot prior to distribution, for identity and strength as a condition of lot release. It also failed to provide active ingredient identity and strength test results or retain samples to support the quality of the drugs distributed to the United States.
- The company did not adequately test incoming components for their identity. Rather, it relied on Certificates of Analysis (COA) from unqualified suppliers and would seek out a laboratory that could perform identity testing on each batch of its active ingredient. Again, the company failed to demonstrate how it could make and control products and "establish the reliability of … suppliers" if it intended to use their COA to evaluate the adequacy of the components. (This is not a complete list of deficiencies identified by FDA.)
- FDA recognized that the contractor delegated certain responsibilities. However, this delegation did not exonerate the company from fulfilling its regulatory obligations. The agency wrote:

> Drugs must be manufactured in conformance with CGMP. FDA is aware that many drug manufacturers use independent contractors, such as production facilities, testing laboratories, packagers, and labelers. FDA regards contractors as extensions of the manufacturer.
>
> You are responsible for the quality of drugs you produce as a contract facility, regardless of agreements in place with product owners. You are required to ensure that drugs are made in accordance with section 501(a)(2)(B) of the FD&C Act for safety, identity, strength, quality, and purity. [Citing FDA's guidance document, *Contract Manufacturing Arrangements for Drugs: Quality Agreements*.]

1 The Warning Letter can be accessed at www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm612483.htm

- The agency recommended the company engage a quality consultant. However, FDA made clear (and as we remind clients):

Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.

- It is worth noting that FDA reiterated its enforcement tools, which can be particularly detrimental to companies based outside of the U.S.
    - placement on Import Alert and refusal to admit products into the U.S. from the site where the non-compliant activity is occurring
    - withholding of approval of marketing applications or supporting an existing drug company as a drug manufacturer
    - a "recommendation" to engage a consultant (but not as a substitute for the company's own compliance)

AGG Observations

- We continue to see continued enforcement against companies importing products into the U.S. (or making products for use in U.S. goods). FDA has many enforcement tools, beyond the issuance of a Warning Letter.
- FDA permits companies to use contract manufacturers and companies to delegate to certain manufacturing or testing operations. However, as we have written and counseled previously, such delegation will not exonerate a company from its regulatory requirements.
- On a related note, many companies may enter into a contract manufacturing agreement, and FDA recognizes these agreements. It is important to remember, though, that FDA will not excuse non-compliance, because a contract was silent or parties point to a contract; the agency will look to its rules first and then evaluate whether the agreement follows suit.

Who me? Yes, you. Couldn't be? Might just be.

Authors and Contributors

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 (AGG), an Am Law 200 law firm with 165 attorneys in **Atlanta** and **Washington, DC**, takes a "business sensibility" approach when advising clients. AGG provides industry knowledge, attention to detail, transparency and value to help businesses and individuals achieve their definition of success. AGG's transaction, litigation, regulatory and privacy counselors serve clients in healthcare, real estate, litigation, business transactions, fintech, global commerce, government investigations and logistics and transportation. AGG subscribes to the belief "not if, but how.®"
Visit us at 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/**