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FDA ALERT

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FDA Issues Pharmacy Related Compounding Regulations and Guidance Documents

By Ned Milenkovich and Harold Hilborn

On July 1, 2014, the Food and Drug Administration (FDA) released several documents applicable to compounding pharmacies, which are in the business of preparing custom-tailored drugs intended for patients. The first document is draft interim guidance that describes the FDA's expectations regarding compliance with current good manufacturing practice requirements. It focuses on requirements related to assuring the sterility of sterile compound drug products and the general safety of compounded drugs. As interim guidance, the draft is not legally binding. The second document provides final guidance that explains how the FDA intends to enforce the provisions of Section 503A of the Food, Drug, & Cosmetic Act pending the drafting of rules. As guidance, the document is not legally binding. The third document is a proposed rule that would revise the current list of drug products that cannot be compounded because they have been found to be unsafe or ineffective. That proposed rule is now open to public comment. The last document is a notice that the FDA is reopening the nomination process for lists of active drug ingredients that may be included in compounded drugs.

The FDA issued these documents in connection with the implementation of the Drug Quality and Security Act, which Congress passed last year in response to the fungal meningitis outbreak linked to a Massachusetts compounding pharmacy. The documents are available on the FDA website at: (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm403507.htm).

Roetzel & Andress counts among its ranks partners and counsel, including former Department of Justice, Federal Bureau of Investigations, and Drug Enforcement Administration personnel, focused on providing legal counseling for healthcare providers throughout the country. Additionally, we stand ready to advise you concerning your compliance and litigation needs in this heavily regulated arena.

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