CLIENT ALERT

FDA Issues Final Guidance Aimed at Alleviating COVID-19 Drug Shortages through Outsourcing Facilities

Apr.21.2020

Due to increased demand and supply interruptions stemming from the ongoing pandemic, many hospitals have been experiencing difficulties in accessing FDA-approved drug products needed to treat patients infected with COVID-19. These drugs are vital to treat hospitalized COVID-19 patients, who have, for example, been intubated or need the medications in connection with other treatment procedures. In an effort to alleviate drug shortages, the U.S. Food and Drug Administration (FDA) has issued a new Final Guidance outlining proactive steps the agency is taking to alleviate these drug shortages.

The guidance notes that FDA ordinarily tries to address potential and actual drug shortages by restoring supplies through the global pharmaceutical supply chain. However, the pandemic has resulted in "unprecedented disruptions to, and demands on, the global pharmaceutical supply chain," and, accordingly, "additional flexibility is temporarily needed to ensure that treatment options are available when hospitals are unable to obtain FDA-approved drugs use for hospitalized patients with COVID-19."

Therefore, FDA is turning to outsourcing facilities to help mitigate shortages by temporarily lifting requirements that these facilities ordinarily must adhere to in compounding drug products. Under ordinary circumstances, the Food, Drug and Cosmetic (FDC) Act provides that outsourcing facilities are permitted to compound drugs that are identical or nearly identical to FDA-approved products as long as the products appear on the FDA's drug shortage list. Outsourcing pharmacy facilities have the capacity to sterilely manufacture higher quantities of drugs, but are stringently regulated and subject to heightened FDA review requirements—for example, they must register with FDA, undergo FDA inspections, abide by current good manufacturing process (CGMP) requirements, and adhere to other conditions.

These requirements have now been provisionally relaxed, so that compounding facilities may: (a) compound drug products that are essentially a copy of an approved drug, whether or not it is on the drug shortage list; (b) use bulk drug substances that are not on FDA's 503B Bulks List; and (c) not meet CGMP requirements with regard to product stability testing and the establishment of drug expiration dates. However, the following criteria must be met:

1. Compounded drug products must appear on the approved list found in Appendix A of the guidance, and must contain only one of the active ingredients listed there. Appendix A includes, but is not limited to, pain medication like fentanyl citrate, sedatives like midazolam hydrochloride and dexmedetomidine hydrochloride, and paralytics like vecuronium bromide;
2. Compounded drug products must be provided directly to a hospital that informs the outsourcing facility that it (i) is treating patients with COVID-19, and (ii) has made reasonable attempts to obtain the FDA-approved version of the product through conventional means;
3. Bulk drug substances used to compound the drug products must comply with certain sections of the FDC Act which relate to conforming with United States Pharmacopeia monograph standards, sourcing from approved facilities, and providing certificates of analysis; and

4. Outsourcing facilities' practices for stability testing and establishing expiration dates adhere to conditions described in Appendices B and C of the guidance, with certain exceptions for specific types of drugs. Generally, Appendix B describes FDA's recommendations for outsourcing facilities regarding stability testing and drug expiration dating/beyond use dating. Appendix C more thoroughly addresses the conditions under which FDA will exercise enforcement discretion regarding stability testing and drug expiration.

In the meantime, FDA asserts that it is "using all of the agency's authorities to restore or increase the supply of FDA-approved drugs" by actively "working with manufacturers in the global pharmaceutical chain to prevent and mitigate drug shortages and access problems."

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