crowell moring

CLIENT ALERT

FDA Turns to 503A Compounding Facilities to Mitigate COVID-19 Drug Shortages

May.01.2020

In another step towards helping ease shortages in medications needed to treat hospitalized COVID-19 patients, the United States Food and Drug Administration (FDA) issued a Final Guidance regarding non-registered compounding facilities' role in alleviating COVID-19 drug shortages. In a prior Final Guidance issued last week, FDA noted that it would ease regulatory restrictions on 503B outsourcing facilities in order to allow these facilities to compound drugs currently in shortage for COVID-19 patients. Similarly, this new guidance eases restrictions on compounding facilities that are not registered as outsourcing facilities. The Agency noted that this was an additional step towards mitigating drug shortages, as "FDA understands that during the COVID-19 public health emergency, even with the regulatory flexibility provided in the guidance for [Outsourcing Facilities], the drugs compounded by outsourcing facilities also may not be sufficient, in some circumstances, to meet urgent needs."

FDA acknowledged that state-licensed or federal compounding facilities that are not registered with FDA are regulated under different conditions and are not subject to Current Good Manufacturing Practices (cGMP). Further, these facilities are required to dispense each compounded drug product to an individual patient based on the receipt of a valid prescription order. Both registered outsourcing and non-registered facilities ordinarily may not compound FDA-approved commercially available drug products.

However, as emphasized in the previous guidance, FDA acknowledged the difficulties hospitals are facing to obtain FDA-approved drug products used for patients with COVID-19. Therefore, FDA does not intend to take enforcement action against non-registered compounding facilities for compounding a drug that is essentially a copy of a commercially available drug, or for providing a drug to a hospital without obtaining a patient-specific prescription if certain criteria are 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. The hospital is treating a COVID-19 patient and has made reasonable attempts to obtain (i) adequate supplies of an FDA-approved drug product containing the same active ingredient for the same route of administration, and (ii) adequate supplies of a product made by an outsourcing facility containing the same active ingredient for the same route of administration;
3. The compounded drug product is labeled with a default beyond-use-date (BUD) in accordance with Appendix B of the guidance with some exceptions requiring a shorter BUD;
4. If the pharmacy and hospital are not owned and controlled by the same entity, the pharmacy must (i) mark the order as one dispensed to a COVID-19 patient, and (ii) request that the hospital provide patient records that identify the patients to whom the drugs were administered, to the extent the law permits, and document the request within one month after the pharmacy sends the product; and

5. Before dispensing the compounded product, a state-licensed facility must notify the applicable state authority, and the state authority must inform the pharmacy that it does not object to the facility providing the drug product to the hospital without a patient-specific prescription. The state authority is the entity that (i) regulates pharmacy compounding in the state where the pharmacy is located, and (ii) if different, the state authority that regulates pharmacy compounding in the state where the hospital is located.

FDA recommends that hospitals obtaining non-patient-specific supplies of drugs listed in Appendix A maintain records of both the entity supplying the drug products and the patients that receive such products. FDA also encourages hospitals to provide to the pharmacies, to the extent allowed by applicable laws, records that identify the patients to whom the drugs were administered. Such records may be important to allow follow-up if quality issues or adverse events are reported associated with drugs the pharmacy has provided.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

John Fuson
Partner – Washington, D.C.
Phone: +1 202.624.2910
Email: jfuson@crowell.com

Anne Elise Herold Li
Partner – New York
Phone: +1 212.895.4279
Email: ali@crowell.com

Chalana N. Damron
Counsel – Washington, D.C.
Phone: +1 202.624.2566
Email: cdamron@crowell.com

Mariam Sarwar
Associate – Los Angeles
Phone: +1 213.443.5570
Email: msarwar@crowell.com