FDA Details Expectations for Drug Compounders

The U.S. Food and Drug Administration (FDA) on July 1 issued several policy documents on compounded drug products for human use as part of the agency's effort to implement the compounding provisions of the Drug Quality and Security Act (DQSA) of November 2013. New policy documents include draft interim guidance, a proposed rule, final guidance, and 2 revised requests for nominations for the bulk drug substances lists.

"Providing clarity to the compounding industry on the agency's expectations for these unapproved drug products is a priority for the agency," said Janet Woodcock, MD, director of the FDA Center for Drug Evaluation and Research. "These actions are essential next steps in providing the compounding industry with the appropriate tools to comply with the law and advancing the FDA's efforts to continue protecting patients."

Documents now available include:

(1) Draft interim guidance that describes FDA expectations for compliance with current good manufacturing practice (CGMP) requirements for facilities that compound human drugs and register with the FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The guidance focuses on CGMP requirements related to sterility assurance of sterile drug products and the general safety of compounded drug products. The guidance is available at: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM403496.pdf.

(2) A proposed rule that would revise the current FDA list of drug products that may not be compounded because the drug products have been withdrawn or removed from the market because they were found to be unsafe or not effective. The proposed rule would modify the description of 1 drug product on the list and add 25 drug products to the list. The proposed rule is available at: www.federalregister.gov/articles/2014/07/02/2014-15371/additions-and-modifications-to-the-list-of-drug-products-that-have-been-withdrawn-or-removed-from. The list set forth in the proposed rule would apply to both compounders and outsourcing facilities seeking to compound drugs for human use under sections 503A and 503B, respectively.

(3) Final guidance for individuals or pharmacies that intend to compound drugs under section 503A, now that the FD&C Act has been amended by the DQSA. The guidance generally restates the provisions of section 503A, describes the FDA's interim policies with respect to specific provisions that require implementing regulations or other actions, and contains a nonexhaustive list of potential enforcement actions against individuals or pharmacies that compound human drug products in violation of the FD&C Act. The final guidance is available at: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf.

(4) Two *Federal Register* notices stating that the FDA is reopening the nomination process for 2 lists of bulk drug substances (active pharmaceutical ingredients) that may be used to compound drug products. The lists are for drug products compounded in accordance with sections 503A and 503B of the FD&C Act. In response to a December 2013 request for nominations, the agency received nominations that were not for bulk drug substances used in compounding and that did not provide sufficient information to justify inclusion of the substances on the lists. The FDA is providing more detail on what information is needed to evaluate nominations for placement on the lists. More information is available at www.federalregister.gov/articles/2014/07/02/2014-15367/bulk-drug-substances-that-may-be-used-to-compound-drug-products-in-accordance-with-section-503a-of and www.federalregister.gov/articles/2014/07/02/2014-15373/bulk-drug-substances-that-may-be-used-to-compound-drug-products-in-accordance-with-section-503b-of.

The draft interim guidance and proposed rule were made available for public comment until September 1, and the dockets will be open for the public to nominate bulk drug substances for compounding under section 503A or 503B until October 1.