Key FDA Guidance Documents For Section 503B Outsourcing Facilities

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In late November, 2014, the Food and Drug Administration (FDA) released two final guidance documents and one revised draft guidance relating to drug compounding by outsourcing facilities. These new guidance documents collectively provide insight into registration of outsourcing facilities, the annual establishment fees that must be paid by outsourcing facilities, and how electronic drug reporting for these facilities will operate.

The guidance documents stem from the passage of the Drug Quality and Security Act (DQSA) on November 27, 2013. The DQSA added new section 503B to the Federal Food, Drug, and Cosmetic Act (FD&C Act).[1] This new statutory provision allows a drug compounder to elect to become an "outsourcing facility"[2] and register with FDA. The legislation, which also added a revised section 503A to the FD&C Act, distinguishes between traditional drug compounders, who are engaged in filling patient-specific prescriptions and those compounding facilities that engage in larger-scale compounding, often with national distribution. An outsourcing facility, unlike traditional compounders, is not required to be a licensed pharmacy. Section 503B provides that each outsourcing facility must report to FDA certain information about the drug products it compounds. So long as the requirements in section 503B are met, drug products compounded in an outsourcing facility can qualify for exemptions from the FDA approval requirements for new drugs and the requirement to label drug products with adequate directions for use. Nevertheless, outsourcing facilities will be inspected by FDA and must comply with other provisions of the FDCA, including current good manufacturing practice (cGMP) requirements.[3]

A brief summary of the three guidance documents follows:

Final Guidance "Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act".[4]

This final guidance provides basic information to assist drug compounders that elect to register as an outsourcing facility, including information on the details that should be included in the registration and how to withdraw a registration with FDA. The final guidance notes that registration should be completed electronically, but a waiver is available if there is a reason the facility cannot register electronically. Also, FDA confirms that registration as an outsourcing facility is not effective until FDA assesses the registration fee and that fee is paid.

Final Guidance "Fees for Human Drug Compounding Outsourcing Facilities under Section 503B and 744K of the FD&C Act"[5]

This final guidance specifies the annual establishment fees that must be paid when an entity voluntarily registers as an outsourcing facility. Beginning with fiscal year (FY) 2015, an outsourcing

1 21 U.S.C. § 353B.

2 The term "outsourcing facility" means a facility in one geographic location or address that (1) is engaged in the compounding of sterile drugs; (2) has elected to register as an outsourcing facility; and (3) complies with the requirements of section 503B.

3 FDA issued a draft guidance on this topic on July 2, 2014, which is available at https://www.federalregister.gov/articles/2014/07/02/2014-15370/draft-guidance-for-industry-on-current-good-manufacturing-practice-interim-guidance-for-human-drug

4 This final guidance is available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377051.pdf

5 This final guidance document is available at http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm391102.pdf

facility must pay an annual establishment fee during the October 1 to December 31 registration period. Should an outsourcing facility not pay the required fees, the drugs compounded at the facility will not qualify for the section 503B exemptions to the new drug approval requirements and the adequate labeling requirements. The final guidance also addresses the topics of reinspection fees, annual fee adjustments, and how to qualify as a small business to qualify for a reduction in the annual establishment fee.

Revised Draft Guidance "Electronic Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act"[6]

Section 503B requires outsourcing facilities to report information on the drugs they compound to FDA upon registration and thereafter twice yearly. This revised draft guidance supersedes an earlier draft guidance issued by FDA to establish interim product reporting requirements. FDA's revised draft guidance specifies that the information on compounded drugs must be submitted electronically (unless a waiver is obtained) between June 1 and June 30, covering the period between December 1 and May 31; and between December 1 and December 31, covering the period between June 1 and November 30. These reports must include the following information for each drug compounded:

- Active ingredient and strength of that ingredient per dose
- Source of the active ingredient (bulk or finished drug)
- National Drug Code (NDC) number for each source drug or bulk active ingredient
- Dosage form and route of administration
- Package description
- Number of individual units in the smallest saleable package
- NDC number of the final product, if assigned.

FDA will accept comments on the revised draft guidance through January 23, 2015.

The implementation of Section 503B is designed to provide greater oversight and confidence in the sterile compounding industry. There remain significant questions regarding FDA's expectations for outsourcing facilities, but the publication of these two final guidance documents and the revised draft guidance represent a major step in assisting outsourcing facilities compliance with the stated goals of section 503B.

6 This revised draft guidance document is available at http://www.fda.gov/downloads/drugs/newsevents/ucm424303.pdf

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