1: BACKGROUND

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Compounding Quality Act (CQA) (Title I of the DQSA, Public Law 113-54), created a new category of regulated entity, human drug compounding outsourcing facilities. Under section 503B of the FD&C Act, a human drug compounder can elect to register with the Food and Drug Administration (FDA) as an outsourcing facility. The CQA authorizes FDA to assess and collect fees from entities that register with FDA as outsourcing facilities. FDA spends fee revenues to hire, support, and maintain personnel for the oversight of these outsourcing facilities.

An outsourcing facility is defined as "a facility at one geographic location or address that (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; (iii) and complies with all of the requirements of this section." (Section 503B(d)(4) of the FD&C Act.)

Outsourcing facilities are subject to current good manufacturing practice (CGMP) requirements under section 501(a)(2)(B) of the FD&C Act and will be inspected by FDA on a risk-based schedule (see sections 503B(a) and 503B(b)(4)). Drug products compounded by or under the direct supervision of a licensed pharmacist at an outsourcing facility may be able to qualify for exemptions from the following three sections of the FD&C Act: (1) section 505 (concerning FDA approval of drugs); (2) section 502(f)(1) (concerning the labeling of drug products with adequate directions for use); and section 582 (concerning the drug supply chain security requirements). An outsourcing facility is not required to be a licensed pharmacy and may or may not obtain patient-specific prescriptions.

To qualify for the exemptions, certain conditions must be met. For example, outsourcing facilities must report the drugs that they compound, as well as certain adverse events, to FDA. They must not compound drugs that are essentially copies of one or more approved drugs, and the compounded drugs must not be sold or transferred by an entity other than that outsourcing facility that compounded them. The CQA lists the conditions under which drugs compounded by outsourcing facilities can qualify for the exemptions in section 503B and is available on FDA's website.[1]

Under the CQA, outsourcing facility fees shall be used to supplement and not supplant any other Federal funds available to carry out the activities relating to outsourcing facility oversight (section 744K(d) and section 744K(e)). Therefore, the fees are used to augment appropriations that FDA uses for oversight of compounding outsourcing facilities.

The CQA requires FDA to submit an annual report to Congress no later than 120 days after each fiscal year (section 744K(h) of the FD&C Act). As required by statute, this report presents: 1) a description of fees assessed; 2) a description of fees collected; 3) a summary description of entities paying the fees; 4) a description of the hiring and placement of new staff; 5) a description of the use of fee resources to support inspecting outsourcing facilities; and 6) the number of inspections and reinspections of facilities performed each year.

[1] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm