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FDA Issues Three Guidance Documents for Outsourcing Facilities

FDA has announced the availability of two Final Guidance documents and one revised Draft Guidance related to Section 503B outsourcing facilities. FDA published the three guidance documents Friday afternoon. The Final Guidances address registration requirements for outsourcing facilities and corresponding registration fees. The Draft Guidance proposes standards for the reporting of products compounded by outsourcing facilities.

The first Final Guidance, "Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act," addresses 503B outsourcing facility registration under new provisions added to the Federal Food, Drug, and Cosmetic Act (the FDCA), as amended by the Drug Quality and Security Act (DQSA). The guidance is intended to assist human drug compounders that elect to register as outsourcing facilities in registering, re-registering, or de-registering with FDA. The guidance provides information on how an outsourcing facility should submit facility registration information electronically in structured product labeling (SPL) format using FDA's electronic submission system.

The second Final Guidance, "Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act," addresses the fees applicable to 503B outsourcing facilities. This guidance is intended for entities that compound human drugs and elect to register as outsourcing facilities under the FDCA provisions added by the DQSA. Entities that elect to register as outsourcing facilities must pay certain fees to be considered outsourcing facilities. This guidance describes the annual establishment fee, the reinspection fee, annual adjustments to fees required by law, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee.

The revised Draft Guidance, "Electronic Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act," updates reporting instructions for drug compounders that choose to register as outsourcing facilities. Such compounders must report information on the drugs they have compounded in Structured Product Labeling (SPL) format using FDA's electronic submissions system. This revised draft guidance supersedes a draft guidance entitled "Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Comments on the revised Draft Guidance should be submitted by January 23, 2015.

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