4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1429]

Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; Final Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry entitled "Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act." The guidance addresses new provisions in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), 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. This guidance reflects the Agency's current thinking on the issues addressed by the guidance.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the final guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the final guidance document. Submit electronic comments on the final guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Soo Jin Park, Drug Registration and Listing Team, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act." This guidance is being issued consistent with the new authority conferred to FDA in the DQSA (Public Law 113-54). In that legislation, Congress created a new category for certain facilities that compound human drugs called "outsourcing facilities." Section 503B(d)(4) of the FD&C Act (21 U.S.C. 353B(d)(4)) defines an outsourcing facility, in part, as a facility that complies with all of the requirements of section 503B, including registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section

501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs). This guidance is intended to assist compounding facilities that wish to register as outsourcing facilities to register with FDA and discusses the process for registering, re-registering, and de-registering.

In the Federal Register of December 4, 2013 (78 FR 72899), FDA issued a notice announcing the availability of the draft version of this guidance. That draft guidance set forth an interim and electronic submission method for human drug compounders that elect to register as outsourcing facilities. The comment period on the draft guidance ended on February 3, 2014. FDA received nine comments on the draft guidance. Some of the received comments raised issues that were not directly pertinent to the topics addressed in this guidance. FDA intends to consider those comments as they relate to issues being addressed in other policy documents being developed by the Agency.

In response to received comments or on its own initiative, FDA made the following changes as it finalized this guidance: (1) We included a phone number for a point of contact; (2) we deleted reference to an alternative interim registration method; (3) we added information on how a registered outsourcing facility can de-register; (4) we clarified what registration information will be made public; (5) we clarified the standard to be used to grant a waiver of the electronic submission requirements; and (6) we made grammatical and other minor editorial changes to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the

public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

This guidance contains collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information have been approved under OMB control number 0910-0777.

III. Comments

Interested persons can submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments can be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: November 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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