DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0030]

Compounding of Human Drug Products under the Federal Food, Drug, and Cosmetic Act; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to receive information, recommendations, and comments on matters related to the Agency's regulation of compounding of human drug products under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This docket is intended for general comments related to human drug compounding that are not specific to documents or issues that are the subject of other dockets.

DATES: Comments may be submitted to this docket at any time.

ADDRESSES: You may submit comments, identified by Docket No. [FDA-2015-N-0030], by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written comments in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. [FDA-2015-N-0030]. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philantha Bowen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg.51, rm. 5175, Silver Spring, MD 20993-0002, 301-796-2466.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or

abbreviated new drug applications). Previously, the conditions of section 503A of the FD&C Act also included restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug and the solicitation of prescriptions for compounded drugs. These provisions were challenged in court and held unconstitutional by the U.S. Supreme Court in 2002.[1]

On November 27, 2013, President Obama signed the Drug Quality and Security Act(DQSA) (Public Law 113-54), which contains important provisions relating to the oversight of human drug compounding. This new law removes from section 503A of the FD&C Act the provisions that had been held unconstitutional by the U.S. Supreme Court in 2002. By removing these provisions, the new law clarifies that section 503A of the FD&C Act applies nationwide. In addition, the DQSA adds a new section, 503B, to the FD&C Act (21 U.S.C. 353b) that creates a new category of "outsourcing facilities". Outsourcing facilities, as defined in section 503B of the FD&C Act, are facilities that meet certain conditions described in section 503B, including registration with FDA as an outsourcing facility. If these conditions are satisfied, a drug compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1), (2) section 505, and (3) section 582 (21 U.S.C. 360eee), but not section 501(a)(2)(B).

Since enactment of the DQSA, FDA has sought public comment on a number of specific human drug compounding issues and has published several Federal Register notices seeking public input. These have included notices inviting comment on the registration process and product reporting requirements for human drug compounding outsourcing facilities (78 FR 72899 and 78 FR 72897), requesting nominations for the list of drugs that present demonstrable difficulties for compounding (78 FR 72840), and seeking input on other specific matters. A

[1] See Thompson v. Western States Med. Ctr., 535 U.S. 357 (2002).

complete list of the human drug compounding policy documents issued by the Agency for public comment can be found at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm. The Agency will continue to seek public comment on specific documents and issues through future Federal Register notices. The Agency recognizes, however, that it would be useful to have a docket available for submissions of any information related to human drug compounding that may be unrelated to the specific issues and documents published for public comment.

II. Establishment of a Docket

FDA is establishing a public docket so that anyone can share information, research, and ideas on any matters related to human drug compounding that are not specific to the documents or issues addressed in other dockets. This information will give the Agency insight into stakeholders' experiences and views regarding human drug compounding as the Agency works to implement sections 503A and 503B of the FD&C Act.

This docket will be open for comment simultaneously with a number of other dockets that are specific to particular human drug compounding documents or issues (see http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/default.htm for a list of specific human drug compounding policy documents open for public comment). Please do not submit comments to this general docket that have already been submitted to specific dockets. Such submissions are duplicative and not helpful to the Agency. If comments on particular documents or issues are submitted to this docket rather than the docket specifically opened for the particular document or issue, the comment might not be considered as the specific documents are being finalized and issues considered. FDA will not respond to

questions or requests submitted to this docket but will consider any information submitted in its work to implement the law.

Information in the docket will be publicly available. Therefore, we remind commenters not to submit personal or confidential information.

Interested persons may submit either electronic comments 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 the brackets in the heading of this document. Received comments may 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.

Dated: March 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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