will be posted to the docket at *http://www.regulations.gov*.

V. 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: March 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05347 Filed 3–6–15; 8:45 am]

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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) (Pub. L. 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 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/GuidanceCompliance RegulatoryInformation/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/*

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

guidancecompliance regulatoryinformation/pharmacy compounding/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.

[FR Doc. 2015–05376 Filed 3–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2015–0031]

Missouri River Waterways Analysis and Management System

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting and request for comments.

SUMMARY: Coast Guard Sector Upper Mississippi River will hold a public listening session to present, and receive feedback on, the Missouri River Waterways Analysis and Management System (WAMS) study. The WAMS study will review and assess waterborne commerce as well as safe commercial and recreational navigation with a focus on the existing aids to navigation in Missouri River system from Sioux City, IA to St. Louis, MO. This listening session will be open to the public.

DATES: This listening session will be held in Smithville, MO on February 25, 2015, from 10:00 a.m. to 12:00 p.m. If all interested participants have had an opportunity to comment, the session may conclude early. Written comments and related material may also be presented to Coast Guard personnel specified at that meeting. Comments and related materials submitted after the meeting must be received by the Coast Guard on or before April 10, 2015.

ADDRESSES: The listening session will be held at the Jerry Litton Visitors Center, (Smithville Lake) 16311 DD Hwy., Smithville, MO 64089.

Submit written comments identified by docket number USCG–2015–0031 using one of the listed methods, and see **SUPPLEMENTARY INFORMATION** for more information on public comments. To avoid duplication, please use only one of these methods.

- *Online—http://www.regulations.gov* following Web site instructions.
- *Fax*—202–493–2251.
- *Mail* or *hand deliver*—Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Hours for hand delivery are 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays (telephone 202–366–9329).

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Kevin Brensinger, Coast Guard; telephone 314–269–2548, email *SUMRWaterways@uscg.mil.* For information about viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826, toll free 1–800–647–5527.

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

We encourage you to participate in this listening session by submitting comments (or related material) on Missouri River Waterways Analysis and Management System study.

We recommend using the user survey document under docket number USCG–2015–0031 to provide comments. You should provide personal contact information so that we can contact you if we have questions regarding your comments; but please note that all comments will be posted to the online docket without change and that any personal information you include can be searchable online (see the **Federal Register** Privacy Act notice regarding our public dockets, 73 FR 3316, Jan. 17, 2008).

Mailed or hand-delivered comments should be in an unbound 8½ x 11 inch format suitable for reproduction. The Docket Management Facility will acknowledge receipt of mailed comments if you enclose a stamped, self-addressed postcard or envelope with your submission.

Documents mentioned in this notice, and all public comments, may be found in our online docket at *http://www.regulations.gov* and can be viewed by following the Web site's instructions. You can also view the docket at the Docket Management Facility (see the mailing address under **ADDRESSES**) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For information on facilities or services for individuals with disabilities or to request special assistance at the listening session, contact Kevin Brensinger at the telephone number or email address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Basis and Purpose

The Waterways Analysis and Management System was implemented to ensure a complete and organized process for matching waterway attributes and services, most significantly the aids to navigation system, with user needs. The Missouri River study includes navigable waters from Sioux City, IA to St. Louis, MO and specifically targets the navigation channel, marking of the navigation channel, movement of commerce and navigation support for the diverse uses of the river. WAMS studies are conducted periodically to better understand users' needs and facilitate safe and effective waterways. Some of the aspects addressed by WAMS are:

- Are all the aids necessary?
- Should aids be added, changed or removed?
- Is the right aid being used for the job?
- Are the aids marked in a correct and visible manner?
- Are these aids being used properly by both the Coast Guard and the waterway users?

It is the intent of Coast Guard Sector Upper Mississippi River to collect comments and materials from this listening session, along with navigation surveys and other information, to establish and preserve the reasonable needs of navigation on this river.

This notice is issued under authority of 5 U.S.C. 552(a).