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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Pharmacy Compounding Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pharmacy Compounding Advisory Committee

General Function of the Committee: To provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

Date and Time: The meeting will be held on February 23, 2015, from 8:30 a.m. to 5 p.m., and February 24, 2015, from 8:15 a.m. to 3 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: [PCAC@fda.hhs.gov](mailto:PCAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Background: On November 27, 2013, the Drug Quality and Security Act (DQSA) amended section 503A of the FD&C Act to remove certain provisions regarding the advertising and promotion of compounded drugs and the solicitation of prescriptions for compounded drugs that were found to be unconstitutional by the U.S. Supreme Court in 2002. By removing the unconstitutional provisions, the law removed uncertainty regarding the validity of section 503A of the FD&C Act, which is applicable to compounders nationwide.

Section 503A of the FD&C Act ([21 U.S.C. 353a](#)) describes the conditions under which a human drug product compounded for an identified individual patient based on the receipt of a prescription can qualify for exemptions from 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 (CGMP) requirements for drugs); (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 human drug products under new drug applications or abbreviated new drug applications).

The DQSA also created a new section 503B of the FD&C Act, under which a compounder can register as an “outsourcing facility.” Drug products compounded at outsourcing facilities may be able to qualify for exemptions from the FDA approval requirements (section 505 of the FD&C Act) and the requirement to label products with adequate directions for use (section 502(f)(1) of the FD&C Act) but will still be subject to CGMP requirements under section 501(a)(2)(B) of the FD&C Act.

One of the conditions that must be satisfied to qualify for the exemptions under both sections 503A and 503B of the FD&C Act is that the drug that is compounded does not appear on a list of drugs published by the Secretary that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see sections 503A(b)(1)(C) and 503B(a)(4) of the FD&C Act).

Another condition in section 503A of the FD&C Act that must be satisfied to qualify for the section 503A exemptions is that bulk drug substances used in a compounded drug must meet one of the following criteria: (I) Comply with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary of Health and Human Services (the Secretary); or (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary (section 503A(b)(1)(A)(i) of the FD&C Act). FDA will

discuss drugs proposed for inclusion on these two lists with the Pharmacy Compounding Advisory Committee (committee).

Agenda: On February 23, 2015, during the morning session, the committee will discuss proposed revisions to the list of drug products that may not be compounded under the exemptions provided by the FD&C Act because the drug products have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. The list of products is currently codified at 216.24 (21 CFR 216.24), and FDA is proposing to revise and update the list at § 216.24 for purposes of both sections 503A and 503B of the FD&C Act. On July 2, 2014, FDA published a proposed rule that would add 25 drug products to this list and modify the description of one drug product on this list to add an exception (79 FR 37687, July 2, 2014). FDA received two drug-specific comments on the proposed rule. One comment requested that FDA clarify whether the entry for adenosine phosphate that is currently included on the list (all drug products containing adenosine phosphate) is intended to include all three forms of adenosine phosphate (mono-, di-, and triphosphate). The second comment requested that chloramphenicol tablets, 250 milligrams, be excluded from the list. FDA will discuss both of these comments with the committee.

On February 23, 2015, during the afternoon session, and on February 24, 2015, the committee will discuss proposed criteria for developing the list of bulk drug substances that may be used to compound drug products in accordance with section 503A of the FD&C Act and will discuss six substances nominated for inclusion on the list. On December 4, 2013, and July 2, 2014, FDA published notices in the Federal Register (78 FR 72841 and 79 FR 37747) soliciting nominations for this list. At this first meeting of the committee, FDA intends to discuss the following nominated bulk drug substances: Cantharidin, diphenylcyclopropenone, piracetam,

silver protein mild, squaric acid dibutyl ester, and thymol iodide. The nominators of these substances will be invited to make a short presentation supporting the nomination. Other nominated substances will be discussed at future committee meetings.

FDA intends to make background material available to the public at no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 9, 2015. Oral presentations from the public will be scheduled between approximately 10:15 a.m. to 10:45 a.m. and 3:35 p.m. to 3:50 p.m. on February 23, 2015, and between approximately 9:30 a.m. to 9:45 a.m. and 11:45 a.m. to noon on February 24, 2015. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 12, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open

public hearing session. The contact person will notify interested persons regarding their request to speak by February 13, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jayne E. Peterson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 21, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

4164-01-P