



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Pharmacy Compounding Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmacy Compounding Advisory Committee (PCAC). The general function of the committee is to provide advice on scientific, technical, and medical issues concerning drug compounding, as well as any other product for which FDA has regulatory responsibility, and to make appropriate recommendations to the Agency. The meeting will be open to the public.

DATES: The meeting will be held on November 3, 2016, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Cindy Hong, 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, 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: 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 in a State licensed pharmacy or a Federal facility, or licensed physician, to be exempt from the following three sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act): (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) concerning current good manufacturing practice (CGMP); (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 (NDAs) or abbreviated new drug applications (ANDAs).

The Drug Quality and Security Act added a new section 503B to the FD&C Act (21 U.S.C. 353b), which created a new category of compounders termed “outsourcing facilities.” Under section 503B of the FD&C Act, outsourcing facilities are defined, in part, as facilities that meet certain conditions described in section 503B, including registration with FDA as an outsourcing facility. If these conditions are satisfied, a drug product 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) concerning the labeling of drugs with adequate directions for use); (2) section 505 concerning the approval of human drug products under NDAs or ANDAs; and (3) section 582 concerning the drug supply chain security

requirements (21 U.S.C. 360eee-1). Outsourcing facilities are not exempt from CGMP requirements in section 501(a)(2)(B).

One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that a bulk drug substance (active pharmaceutical ingredient) used in a compounded drug product must meet one of the following criteria: (1) Complies 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; (2) if an applicable monograph does not exist, is a component of a drug approved by the Secretary of Health and Human Services (the Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary (the “503A Bulks List”) (see section 503A(b)(1)(A)(i) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that the compounded drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product (see section 503A(b)(3)(A) of the FD&C Act).

A condition that must be satisfied to qualify for the exemptions in section 503B of the FD&C Act is that the compounded drug is not identified (directly or as part of a category of drugs) on a list, published by the Secretary by regulation after consulting with the PCAC, of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients, or the drug is

compounded in accordance with all applicable conditions identified on the list as conditions that are necessary to prevent the drug or category of drugs from presenting such demonstrable difficulties (see section 503B(a)(6)(A) and (B) of the FD&C Act).

FDA intends to discuss with the committee bulk drug substances nominated for inclusion on the 503A Bulks List and drug products nominated for inclusion on the list of drug products that present demonstrable difficulties for compounding under sections 503A and 503B of the FD&C Act (“Difficult to Compound List”).

Agenda: The committee intends to discuss five bulk drug substances nominated for inclusion on the section 503A Bulks List. FDA will discuss the following nominated bulk drug substances: Glycolic acid, trichloroacetic acid, kojic acid, diindolylmethane, and vasoactive intestinal peptide. The chart in this document describes which use(s) FDA reviewed for each of the five bulk drug substances being discussed at this advisory committee meeting. The nominators of these substances will be invited to make a short presentation supporting the nomination.

Drug	Use(s) Reviewed
Diindolylmethane	Treatment of cancer
Glycolic acid	Hyperpigmentation (including melasma) and photodamaged skin
Trichloroacetic acid	Common warts and genital warts
Kojic acid	Hyperpigmentation and as a chelating agent to promote wound healing
Vasoactive intestinal peptide	A condition described as “chronic inflammatory response syndrome”

The committee also intends to discuss drug products that employ transdermal and topical delivery systems, which were nominated for the Difficult to Compound List. The nominators will be invited to make a short presentation supporting the nomination.

FDA intends to make background material available to the public on its Web site 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 will be 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 October 25, 2016. Oral presentations from the public will be scheduled between approximately 9:25 a.m. and 9:35 a.m., 10:25 a.m. and 10:35 a.m., 11:40 a.m. and 11:50 a.m., 1:45 p.m. and 1:55 p.m., 2:50 p.m. and 3 p.m., and 4:10 p.m. and 4:20 p.m. on November 3, 2016. Those individuals interested in making formal oral presentations should notify Cindy Hong 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 October 17, 2016. 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 October 18, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Cindy Hong 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: September 30, 2016.

Janice M. Soreth,

Acting Associate Commissioner,

Special Medical Programs.

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