

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Request for Nominations for Voting Members for the Patient Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for nominations.

SUMMARY: The Food and Drug Administration's (FDA) is requesting additional nominations for members to serve on the Center for Devices and

Radiological Health's (CDRH) Patient Engagement Advisory Committee (the PEAC or Committee). The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, particularly encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received by November 21, 2016, will be given first consideration for membership on the Committee. Nominations received after November 21, 2016, will be considered for nomination to the Committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Committee Membership Nomination Portal: <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> please select Academician/Practitioner in the drop down menu, to apply for membership, or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993-0002, or by FAX: 301-847-8640. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5441, 301-796-8398, FAX: 301-847-8510, Letise.Williams@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members for the Committee. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

I. General Description of the Committee's Duties

The PEAC provides relevant skills and perspectives in order to improve communication of benefits, risks, and clinical outcomes and increase integration of patient perspectives into the regulatory process for medical devices.

The PEAC provides advice on issues relating to medical devices, the regulation of devices, and their use by patients. A variety of topics may be considered by the PEAC, including Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes and device-related quality of life or health status issues.

II. Criteria for Voting Members

The Committee consists of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner of Food and Drugs or designee from candidates who are knowledgeable in areas such as clinical research, primary care patient experience, healthcare needs of patient groups in the United States, or are experienced in the work of patient and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research participants. Prospective members should also have an understanding of the broad spectrum of patients in a particular disease area.

Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this Committee serve as Special Government Employees, with the exception of the representatives from Industry.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the Committee. Self-nominations are also accepted.

Nominations should include a cover letter; a current, complete resume or curriculum vitae for each nominee, including a current business and/or home address, telephone number, and email address if available; and should specify the advisory committee for which the nominee is recommended.

Nominations should also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed

information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 28, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Bioequivalence Recommendations; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled "Bioequivalence Recommendations for Specific Products" that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 5, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way: