

advertising will consist of a print advertisement. The study will assess participants' perceptions of various health risks from using the product, as well as their perceptions of health risk from using the product compared to

smoking cigarettes, using nicotine replacement therapies, and quitting all tobacco and nicotine products. The study will also assess participants' intentions to use the product and their level of doubt about whether tobacco

products are harmful to users' health. Measures of intentions and doubt will be used to help assess the validity of the measures of health risk perception.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Invitation: Young Adults (Ages 18–25) .....	29,000	1	29,000	0.02	580
Invitation: Adults (Ages 26+) .....	29,000	1	29,000	0.02	580
Consent and Screener: Young Adults (Ages 18–25) .....	11,000	1	11,000	0.10	1,100
Consent and Screener: Adults (Ages 26+) .....	16,500	1	16,500	0.10	1,650
Study: Young Adults (Ages 18–25) .....	3,300	1	3,300	0.33	1,089
Study: Adults (Ages 26+) .....	3,300	1	3,300	0.33	1,089
Total .....					6,088

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on prior experience with research that is similar to this proposed study. Approximately 58,000 people will receive a study invitation, estimated to take 1 minute to read (approximately 0.02 hours), for a total of 1,160 hours for invitations. Approximately 27,500 people will complete the informed consent and screener to determine eligibility for participation in the study, estimated to take 6 minutes (0.10 hours), for a total of 2,750 hours for informed consent and screening activities. Approximately 6,600 people will complete the full study, estimated to take 20 minutes (approximately 0.33 hours), for a total of 2,178 hours for study completion activities. The estimated total hour burden of the collection of information is 6,088 hours.

Dated: May 15, 2018.

**Leslie Kux,**

Associate Commissioner for Policy.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2018–N–1708]

**Blood Products 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 Blood Products Advisory Committee. The general function of the

committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

**DATES:** The meeting will be held on June 22, 2018, from 11 a.m. to 4:20 p.m.

**ADDRESSES:** Great Room A, Building 31, FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

**FOR FURTHER INFORMATION CONTACT:**

Bryan Emery or Joanne Lipkind, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, Bldg. 71, Rm. 6132, at 240–402–8054, [bryan.emery@fda.hhs.gov](mailto:bryan.emery@fda.hhs.gov) and Rm. 6270, at 240–402–8106, [joanne.lipkind@fda.hhs.gov](mailto:joanne.lipkind@fda.hhs.gov), respectively, 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 website at <https://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. For those unable to attend in person, the meeting will also be available via webcast. The webcast will be available at the following link: <https://collaboration.fda.gov/bpac0618/>.

**SUPPLEMENTARY INFORMATION:**

**Agenda:** On June 22, 2018, in the morning open session, under Topic 1, the Committee will hear presentations on the research programs in the Laboratory of Emerging Pathogens (LEP), Laboratory of bacterial and TSE Agents (LBTSE), and from the Laboratory of Molecular Virology (LMV) in the Division of Emerging Transfusion-Transmitted Diseases (DETTD), Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), FDA. After the conclusion of the open session, the meeting will be closed to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6).

In the afternoon, in open session, under Topic II, the Committee will hear presentations on the research program in the Hemostasis Branch (HB), in the Division of Plasma Protein Therapeutics (DPPT), Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER), FDA. After the open session, the meeting will be closed to the public to permit discussion where disclosure would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552.b(c)(6).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will

be made publicly available at the venue of the advisory committee meeting, and the background material will be posted on FDA's website 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:** On June 22, 2018, from 11 a.m. to 12:55 p.m. and 2:20 p.m. to 3:45 p.m., the meeting is open to the public. 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 June 15, 2018. Oral presentations from the public will be scheduled between approximately 12:25 p.m. to 12:55 p.m. and from 3:15 p.m. to 3:45 p.m. on June 22, 2018. 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 June 7, 2018. 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 June 8, 2018.

**Closed Committee Deliberations:** On June 22, 2018 between 12:55 p.m. and 1:40 p.m. and between 3:45 p.m. and 4:20 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). During the closed sessions, the Committee will discuss the research progress made by staff involved in the intramural research programs and make recommendations regarding personnel actions and staffing.

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 Bryan Emery at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at

<https://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: May 15, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0001]

#### Advisory Committee; Anesthetic and Analgesic Drug Products Advisory Committee, Renewal

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Anesthetic and Analgesic Drug Products Advisory Committee (the Committee) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until May 1, 2020.

**DATES:** Authority for the Committee will expire on May 1, 2020, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:**

Moon Hee Choi, 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, email: [AADPAC@fda.hhs.gov](mailto:AADPAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Committee. The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and

effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products including analgesics, *e.g.*, abuse-deterrent opioids, novel analgesics, and issues related to opioid abuse, and those for use in anesthesiology and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of anesthesiology, analgesics (such as: abuse deterrent opioids, novel analgesics, and issues related to opioid abuse) epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticandAnalgesicDrugProductsAdvisoryCommittee/default.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: May 15, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-10731 Filed 5-18-18; 8:45 am]

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