

We base our estimate of the average burden per response on review activities familiar to the Agency. Noting that 2 hours per response is a significant amount of time, we are particularly interested in feedback regarding this estimate, including comments regarding how an alternative estimate might be derived.

Dated: September 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-20092 Filed 9-14-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3431]

Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled “Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments” that appeared in the **Federal Register** of September 11, 2018. The document announced a forthcoming public advisory committee meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and establishment of a public docket for comments. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, September 11, 2018 (83 FR 45941), in FR Doc. 2018-19667, on page 45941, the following correction is made:

On page 45941, in the first column, in the header of the document, and also in the third column under *Instructions*, “Docket No. FDA-2018-N-3276” is corrected to read “Docket No. FDA-2018-N-3431”.

Dated: September 11, 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-3236]

Advisory Committee; Oncologic Drugs 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 Oncologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Oncologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until September 1, 2020.

DATES: Authority for the Oncologic Drugs Advisory Committee will expire on September 1, 2020, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Lauren Tesh, 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: ODAC@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 Oncologic Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Oncologic Drugs Advisory 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 data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner.

The committee shall consist of a core of 13 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of general oncology, pediatric oncology, hematologic oncology, immunology oncology, biostatistics, and other related professions. 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/OncologicDrugsAdvisoryCommittee/ucm107395.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: September 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-20108 Filed 9-14-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Pathogen Reduction Technologies for Blood Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Pathogen Reduction Technologies for

Blood Safety.” The purpose of the public workshop is to foster the development and implementation of pathogen reduction technologies for blood components intended for transfusion. The workshop will include presentations and panel discussions by experts from academic institutions, industry, and government agencies.

DATES: The public workshop will be held on November 29, 2018, from 8 a.m. to 5 p.m., and on November 30, 2018, from 9 a.m. to 1 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Loni Warren Henderson or Sherri Revell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-402-8010, email: CBERPublicEvents@fda.hhs.gov (subject line: Pathogen Reduction Technology and Blood Safety).

SUPPLEMENTARY INFORMATION:

I. Background

Pathogen reduction technology has the potential to improve blood safety by reducing or eliminating infectious organisms, including bacteria, viruses, and parasites, from blood components intended for transfusion. FDA granted approvals for use of a pathogen reduction technology platform in manufacturing plasma and apheresis platelets for transfusion. Ideally, pathogen reduction technology should also be available for whole blood and red blood cells. Implementation of safe and effective pathogen reduction technology may also permit alternative donor screening or donation testing strategies in the future. The purpose of the public workshop is to foster the development and implementation of pathogen reduction technologies for all blood components intended for transfusion.

II. Topics for Discussion at the Public Workshop

The first day of the workshop will include presentations and panel discussions on the following topics: (1) Transfusion-transmitted infectious agents and their impact on blood safety; (2) status of pathogen reduction technology for blood components intended for transfusion, including challenges to implementation in the United States; and (3) the development of pathogen reduction technology for whole blood and red blood cells.

The second day of the workshop will include presentations and panel discussions on the following topics: (1) Emerging pathogen reduction technologies and alternative approaches to controlling risk; (2) potential funding opportunities for research; and (3) a summary of all workshop sessions, panel discussions, and future directions.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: <https://www.eventbrite.com/e/pathogen-reduction-technologies-for-blood-safety-public-workshop-tickets-4464956605>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by November 8, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided, beginning at 7 a.m.

If you need special accommodations, due to a disability, please contact Loni Warren Henderson or Sherri Revell no later than November 19, 2018 (see **FOR FURTHER INFORMATION CONTACT**). Request for sign language interpretation or Computer Aided Realtime Translation (CART)/captioning should be made 2 weeks in advance of the event, no later than November 15, 2018. A request for either interpreting or captioning should be sent directly to the FDA Interpreting Services Staff email account: interpreting.services@oc.fda.gov.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Individuals who wish to view the webcast should register for the workshop at [https://www.eventbrite.com/e/pathogen-](https://www.eventbrite.com/e/pathogen-reduction-technologies-for-blood-safety-public-workshop-tickets-4464956605)

[reduction-technologies-for-blood-safety-public-workshop-tickets-4464956605](https://www.eventbrite.com/e/pathogen-reduction-technologies-for-blood-safety-public-workshop-tickets-4464956605). A link to the live webcast will be provided upon registration.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at <https://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/default.htm>.

Dated: September 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the October meeting, the Long-Term Services and Supports Subcommittee will be taking charge of the theme. The topics covered will include: (1) The experience of people with dementia who have special needs due to issues like diversity, geography, and concurrent disorders; (2) How clinical care can be better integrated with community-based supports and services; and (3) Evidence-based behavioral approaches that mitigate the impact of behavioral symptoms of dementia. The meeting will also include