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.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–20091 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:


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–20091 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–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/ucm1077395.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.


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