Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 9000–0074, Contract Funding—Limitation of Costs/Funds, in all correspondence.

Dated: June 14, 2019.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2019–13138 Filed 6–20–19; 8:45 am]

BILLING CODE 6820–EP–P

GOVERNMENT ACCOUNTABILITY OFFICE

Request for Nominations for the Physician-Focused Payment Model Technical Advisory Committee (PTAC)

AGENCY: Government Accountability Office (GAO).

ACTION: Request for letters of nomination and resumes.

SUMMARY: The Medicare Access and CHIP Reauthorization Act of 2015 established the Physician-Focused Payment Model Technical Advisory Committee to provide comments and recommendations to the Secretary of Health and Human Services on physician payment models and gave the Comptroller General responsibility for appointing its members. GAO is now accepting nominations of individuals for this committee.

DATES: Letters of nomination and resumes should be submitted no later than July 19, 2019, to ensure adequate opportunity for review and consideration of nominees prior to appointment. Appointments will be made in October 2019.

ADDRESSES: Submit letters of nomination and resumes by either of the following methods:

Email: PTACcommittee@gao.gov. Include PTAC Nominations in the subject line of the message, or Mail: U.S. GAO, Attn: PTAC Nominations, 441 G Street NW, Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Greg Giusto at (202) 512–8268 or *giustog@gao.gov* if you do not receive an acknowledgement within a week of submission or if you need additional information. For general information, contact GAO's Office of Public Affairs, (202) 512–4800.

Authority: Pub. L. 114–10, Sec. 101(e), 129 Stat. 87, 115 (2015).

Gene L. Dodaro,

Comptroller General of the United States.

[FR Doc. 2019–13249 Filed 6–20–19; 8:45 am]

BILLING CODE 1610–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–TS–19–002, Multi-Site Study of the Health Implications of Exposure to PFAS-Contaminated Drinking Water.

Date: July 24–25, 2019.

Time: 8:30 a.m.–5:00 p.m., EDT.

Place: W Atlanta-Buckhead, 3377 Peachtree Rd, NE, Atlanta, GA 30326.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Mikel Walters, Ph.D., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341, Telephone (404) 639–0913, *MWalters@cdc.gov.*

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–13178 Filed 6–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2778]

Agency Information Collection Activities; Proposed Collection; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for data needed to evaluate requests for threshold of regulation exemptions for substances used in food-contact articles.

DATES: Submit either electronic or written comments on the collection of information by August 20, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 20, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 20, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or

anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–2778 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Threshold of Regulation for Substances Used in Food-Contact Articles—21 CFR 170.39

OMB Control Number 0910–0298—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the FD&C Act; (2) it conforms to the terms of a regulation prescribing its use; or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6) of the FD&C Act, there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The Agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion (ppb). The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances. To determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance;

(5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use.

We use this information to determine whether the food-contact substance meets the threshold criteria:

Description of Respondents: Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (*i.e.,* food packaging and food processing equipment) or of the articles themselves.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 170.39	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Threshold of regulation for substances used in food-contact articles	4	1	4	48	192

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made adjustments to decrease our burden estimate due to the decrease in the number of respondents. The adjustment resulted in decreases of 3 responses and 144 total burden hours.

We estimate that approximately 4 requests per year will be submitted under the threshold of regulation exemption process of § 170.39, for a total of 192 hours. The threshold of regulation process offers an advantage over the premarket notification process for food-contact substances established by section 409(h) of FD&C Act (OMB control number 0910–0495) in that the use of a substance exempted by FDA is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (*e.g.,* use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both Agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and we would not have to review, similar submissions for identical components of food-contact articles used under identical conditions. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Dockets Management Staff and on the internet at *https://www.fda.gov/food/packaging-food-contact-substances-fcs/threshold-regulation-exemptions-substances-used-food-contact-articles.* Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the Agency has previously granted an exemption from the food additive listing regulation requirement.

Dated: June 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13117 Filed 6–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1536]

Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework; Draft Guidance 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 a draft guidance for industry entitled ''Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework.'' The purpose of this guidance is to describe the benefit-risk framework the Agency uses in evaluating applications for opioid analgesic drugs. This guidance summarizes the information that should be included in a new drug application (NDA) for an opioid analgesic drug to facilitate the Agency's benefit-risk assessment.

DATES: Submit either electronic or written comments on the draft guidance by August 20, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–1536 for ''Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly