evaluated by both Center-specific evaluations and a Cross-Center Evaluation. The Center-specific evaluations are designed to collect data on Center-specific processes and outcomes, which are used to support service delivery and continuous quality improvement. The Cross-Center Evaluation is designed to respond to a set of cross-cutting evaluation questions posed by the Children's Bureau. The Cross-Center Evaluation examines: How and to what extent key partners across and within Centers collaborate; whether Center capacity building service interventions are evaluable; the degree to which Centers follow common protocols; what service interventions are delivered and in what services do jurisdictions participate; how satisfied recipients are with services; what outcomes are achieved in jurisdictions receiving Center services and under what conditions are services effective; and what are the costs of services.

The Cross-Center Evaluation uses a longitudinal, mixed methods approach to evaluate Center services as they develop and mature over the course of the study. Multiple data collection strategies are used to efficiently capture quantitative and qualitative data to enable analyses that address each evaluation question. Cross-Center Evaluation data sources for this effort include (1) satisfaction surveys to assess recipient satisfaction with services, such as the Learning Experiences Satisfaction Survey; (2) a leadership interview used to assess perceptions of state child welfare directors, tribal child welfare directors, and CIP directors; and (3) a web-based collaboration survey used to assess perceptions of collaboration within and between the capacity building centers. Center-specific data sources for this effort include (1) assessment tools such as the Center for Tribes Needs and Fit Exploration Tools; and (2) service-specific feedback forms, such as the Center for States Intensive Projects instrument and the Center for Courts CQI Workshops instrument.

Respondents: Respondents of data collection instruments include (1) child welfare and judicial professionals who use the Collaborative's products and online courses, that participate in webinars, virtual or in-person trainings, or peer events, and that receive brief or intensive tailored services from the Centers; (2) all State child welfare directors, and Tribal child welfare directors, and CIP coordinators that receive services from the Centers; and (3) directors and staff of the three Capacity Building Centers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number respondents	Annual number of respondents	Number annual responses per respondent	Average burden hours per response	Total annual burden hours
Webpages and Products Satisfaction Survey	4,680	1,560	1	.08	125
Learning Experiences Satisfaction Survey (single) [1]	1,500	500	1	.33	165
Learning Experiences Satisfaction Survey (intensive) [2]	2,700	900	1	.08	72
Webinars, Events, and In-Person Meetings Satisfaction Survey	16,506	5,502	1	.08	440
Assessment & Capacity Building Plan Satisfaction Survey	1,350	450	1	.066	30
Center for Tribes Contact Form	150	50	1	.05	3
Center for Tribes Demographic Survey	60	20	1	1.75	35
Center for Tribes Needs and Fit Exploration Tool Phase 1	180	30	1	1.5	45
Center for Tribes Needs and Fit Exploration Tool Phase 2	75	25	1	3.0	75
Center for States Information and Referral Survey	36	12	1	.05	1
Center for States Intensive Projects Survey	990	330	1	.33	109
Center for States Constituency Groups Surveys	1,200	400	1	.33	132
Center for States Brief Tailored Services Survey	375	125	1	.33	41
CIP Annual Meeting Survey	600	200	1	.13	26
Center for Courts CQI Workshops Survey	144	48	1	.17	8
Leadership Interview—States, Territories	56	19	*2	1	38
Leadership Interview—CIPs	52	17	*2	1	34
Leadership Interview—Tribes	39	13	*2	1.25	33
Leadership Interview Part II—Tribes	39	13	*2	.67	17
Annual Collaboration Survey	690	230	1	.36	83
Total					1,512

[1] *For Learning Experiences that consist of a single event (e.g., on-line session or in-person training).*
[2] *For more intensive Learning Experiences that require administration of multiple surveys over a series of events, modules, or units.*
* Reflects the total number of responses per the extension period (three years) rather than the number of annual responses per respondent.

Estimated Total Annual Burden Hours: 1,512.

Authority: 42 U.S.C. 5106.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–17775 Filed 8–16–19; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3475]

Nonprescription Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Nonprescription Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing

a docket for public comment on this document.

DATES: The meeting will be held on September 18, 2019, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. 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.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2019–N–3475. The docket will close on September 17, 2019. Submit either electronic or written comments on this public meeting by September 17, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 17, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 17, 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.

Comments received on or before September 4, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments 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–N–3475 for ''Nonprescription Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 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 the 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: Cindy Chee, 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, Fax: 301–847–8533, email: *NDAC@fda.hhs.gov,* 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 FDA'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.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will discuss data submitted by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, to support new drug application (NDA) 208425, for over-the-counter (OTC) marketing of nicotine oral spray (1 milligram (mg) per spray). The proposed OTC use is to reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking. The applicant proposes to label the product for adults 18 years and older. The committee will be asked to consider whether data support an acceptable risk/benefit profile for the nonprescription use of nicotine oral spray (1 mg per spray) by OTC consumers.

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 location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://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. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before September 4, 2019, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 August 26, 2019. 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 August 27, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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 Chee (see **FOR FURTHER INFORMATION CONTACT**) 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: August 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17724 Filed 8–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0093]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Review Transparency and Communication in Reviews of 351(k) Biologics License Applications in Biosimilars User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 18, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0746. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Acts and 351(k) Biologics License Applications in Biosimilars User Fee Act

OMB Control Number 0910–0746—Extension

This information collection supports the above captioned review program (''the Program''). The Program is part of our performance commitment under the fifth and sixth authorizations of the Prescription Drug User Fee Act (PDUFA), which allows us to collect user fees for the review of human drug and biologics applications for FYs 2013 through 2021, and the second authorization of the Biosimilars User Fee Act (BsUFA II), which applies to 351(k) BLAs for FYs 2018 through 2021. The Program is described in detail in FDA's Commitment Letters for PDUFA VI and BsUFA II, available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf* and *https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.*

The Program goals are to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high quality new drugs and biologics. A key aspect of the extension of the Program to BsUFA II is to conduct an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. The BsUFA II Commitment Letter specifies that an independent contractor can conduct the assessments and specifies that they include interviews of sponsors who submit 351(k) BLAs to the Program in BsUFA II. In accordance with the PDUFA V and BsUFA II Commitment Letters, we contracted Eastern Research Group, Inc. (ERG) to conduct independent interviews of applicants after FDA issues a first-cycle action for applications reviewed under the Program. The purpose of these interviews is to collect feedback from applicants on the success of the Program in increasing transparency and communication of reviews during the review process. ERG will anonymize and aggregate sponsor responses before inclusion in the assessments and presentation materials at public meetings. We will publish in the **Federal Register** for public comment