

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Department Workers (Control Restaurants) Visit 3.	Restaurant Environment Observation Form ..	54	1	30/60

Leroy A. Richardson,
 Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Prenatal Alcohol and Other Drug Exposures in Child Welfare (PAODE-CW) Study.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing a data collection activity as part of the Prenatal Alcohol and Other Drug Exposures in Child Welfare (PAODE-CW) Study. The study examines the current state of child welfare practice regarding the identification and provision of services for children with prenatal substance exposures, including alcohol and other drugs.

The descriptive study will document the policies and practices of child welfare agencies and related organizations to identify, assess, and refer to services children who may have been exposed to prenatal substances and/or diagnosed with a resulting condition such as fetal alcohol spectrum

disorders (FASD). The study will document procedures as well as challenges faced and lessons learned to inform the field of practice as well as policy makers, program administrators, and funders at various levels.

The proposed information collection activities consist of semi-structured interviews and surveys conducted at 28 child welfare agency sites. Focus groups conducted at 8 of the 28 sites will gather information on needs, challenges, and strategies to support children with prenatal substance exposures and their families within the child welfare system.

Respondents: State and child welfare agency directors, child welfare staff and supervisors; agency partners and service providers; and family members and caregivers of children who have been prenatally exposed to substances.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Local Agency Staff Interview Protocol—Frontline Only	27.5	1	1	27.5
Local Agency Staff Interview Protocol—Ongoing Only	27.5	1	1	27.5
Local Agency Staff Interview Protocol—Frontline and Ongoing	15	1	1.25	18.75
Local Agency Medical Staff Interview Protocol	14	1	1	14
Local Agency Director Interview Protocol	14	1	1	14
Focus Group of Caregivers	32	1	1.5	48
Local Agency Staff Survey	280	1	.33	92.4
Service Provider Survey	12	1	.33	3.96
Local Agency Data Staff Interview Protocol	6	1	1.5	9

Estimated Total Annual Burden Hours: 255.11.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap 35) Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All

requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to

comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
 Reports Clearance Officer.

[FR Doc. 2017-24420 Filed 11-8-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5994]

Tobacco Products Scientific 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 Tobacco Products Scientific Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on January 24, 2018, from 8:30 a.m. to 5 p.m. and January 25, 2018, from 8 a.m. to 3 p.m.

ADDRESSES: FDA White Oak Conference Center, Building 31, the Great Room (Rm. 1503), 10903 New Hampshire Ave., 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>.

FOR FURTHER INFORMATION CONTACT: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, email: TPSAC@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 Agency's Web site 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: On January 24 and 25, 2018, the committee will discuss modified risk tobacco product applications, submitted by Philip Morris Products S.A. for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks.

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 Web site 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 Web site 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. Written submissions may be made to the contact person on or before January 4, 2018. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m. on January 25, 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 December 27, 2017. 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 December 28, 2017.

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 Caryn Cohen at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site 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: October 31, 2017.

Lauren Silvis,
Chief of Staff.

[FR Doc. 2017-24379 Filed 11-8-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2014-D-2300]

Evaluating Drug Effects on the Ability To Operate a Motor Vehicle; 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 guidance for industry entitled "Evaluating Drug Effects on the Ability to Operate a Motor Vehicle." The purpose of this guidance is to assist sponsors in the evaluation of the effects of psychoactive drugs on the ability to operate a motor vehicle. Driving is a complex activity involving a wide range of cognitive, perceptual, and motor activities. Reducing the incidence of motor vehicle accidents (MVAs) that occur because of drug-impaired driving is a public health priority. This guidance finalizes the draft guidance issued on January 16, 2015, of the same name.

DATES: The announcement of the guidance is published in the **Federal Register** on November 9, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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