The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products (OMB No. 0920–0210, Expiration Date 12/31/2018)—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Cigarette smoking is the leading preventable cause of premature death and disability in our Nation. Each year more than 480,000 deaths occur as the result of cigarette smoking–related diseases. The CDC, Office on Smoking and Health (OSH), has the primary responsibility for the HHS smoking and health program. Since 1986, as required by the Comprehensive Smoking Education Act of 1984, which amended the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1335a, CDC has collected information about the ingredients used in cigarette products. Respondents are commercial cigarette manufacturers, packagers, or importers (or their representatives), who are required by the CSEA to submit ingredient reports to HHS on an annual basis. Respondents are not required to submit specific forms; however, they are required to submit a list of all ingredients used in their products. CDC requires the ingredient report to be submitted by chemical name and Chemical Abstract Service (CAS) Registration Number, consistent with accepted reporting practices for other companies currently required to report ingredients added to other consumer products.

Ingredient reports are due annually on March 31. Information is submitted to CDC by mailing or faxing a written report on the respondent's letterhead. All faxed lists should be followed up with a mailed original. Data may also be submitted to CDC by CD, three-inch floppy disk, or thumb drive. Electronic mail submissions are not accepted. Mail Annual Ingredient Submissions to Attention: FCLAA Program Manager, Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, MS S107–7, Atlanta, GA 30341–3717.

Upon receipt and verification of the annual ingredient report, OSH issues a Certificate of Compliance to the respondent. CDC also uses the information to report to Congress (as deemed appropriate) discussing the health effects of these ingredients. There are no costs to respondents other than their time. The total estimated annualized burden hours are 358. OMB approval is requested for three years.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Business Entities	N/A	55	1	6.5

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–01326 Filed 2–6–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Survey of Head Start Grantees on Training and Technical Assistance (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to conduct a statistically representative survey of directors and managers/coordinators from Head Start grantee organizations regarding their access to and use of training and technical assistance (T/TA) from multiple sources, including ACF's Early Childhood Training and Technical Assistance system. The purpose of the data collection is to inform ACF on three aspects of grantee directors and managers/coordinators T/TA experience: (1) Search and selection of T/TA; (2) receipt of T/TA; (3) and potential relationships between T/TA received and perceived change in practice.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the 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.

ADDRESSES: 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: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Head Start Directors Wave 1 survey addresses the grantee's organizational characteristics, how the organization defines and diffuses T/TA, T/TA received and requested in the prior program year, and overall organizational goals and reflections on T/TA efforts for the current year. The Head Start Managers/Coordinators Wave 2 survey addresses four distinct domains of Head Start activity: (1) Program management and fiscal operations; (2) education; (3) parent and family engagement; and (4) health and wellness. The Wave 2 survey addresses how these activity domains are structured and staffed with the grantee organization, the types of T/TA and resources sought and used to improve practice in each domain, perceptions of usefulness of recent T/TA received, and T/TA priorities for the next program year.

Respondents: Head Start Directors, Head Start Managers/Coordinators.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Wave 1 Head Start Director Survey	1,200	1	.75	900
Wave 2 Head Start Managers/Coordinator Survey	800	1	.75	600

Estimated Total Annual Burden Hours: 1,500.

Comments: 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.

Authority: The Statutory Authority for this data collection is: Section 640(a)(2)(D) and section 649 of the Improving Head Start for School Readiness Act of 2007.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–01428 Filed 2–6–19; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1334]

Opioid Use Disorder: Developing Depot Buprenorphine Products for Treatment; 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 final guidance for industry entitled ''Opioid Use Disorder: Developing Depot Buprenorphine Products for Treatment.'' This guidance reflects the Agency's current thinking regarding drug product development and trial design issues relevant to the study of depot buprenorphine products (*i.e.,* modified-release products for injection or implantation) for the treatment of opioid use disorder. Passive-compliance formulations such as sustained-release injectable depots and implants can provide effective treatment of opioid use disorder in a treatment paradigm that may be less subject to misuse, abuse, or accidental exposure compared to self-administered formulations such as transmucosal tablets and films. This guidance finalizes the draft guidance entitled ''Opioid Dependence: Developing Depot Buprenorphine Products for Treatment'' issued in April 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on February 7, 2019.

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 written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows: