DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0198]

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: FY 2020–2022 Child Care and Development Fund Plan for Tribes (ACF–118A)

Description: The Child Care and Development Fund (CCDF) Plan (the Plan) for Tribes is required from each CCDF Lead agency in accordance with Section 658E of the Child Care and Development Block Grant Act of 1990 (CCDBG Act), as amended, CCDBG Act of 2014 (Pub. L. 113–186), and 42 U.S.C 9858. The Plan, submitted on the ACF–118A, is required triennially, and remains in effect for three years. The Plan provides ACF and the public with a description of, and assurance about the States' and Territories' child care programs. These Plans are the applications for CCDF funds.

This Notice is required by the Paperwork Reduction Act (PRA). The PRA requires Federal agencies to request approval from the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) for any information collection that will ask the same question of ten or more persons. The process includes publication of an initial **Federal Register** Notice (FRN) allowing 60 days for public comments on the initial plan for information collection, the publication of a second FRN allowing 30 days for public comment on the final proposed information collection, and review and approval by the OMB Office of Information and Regulatory Affairs.

The Office of Child Care (OCC) has revised the FY 2020–2022 CCDF Plan Preprint for Tribes to align with the CCDF Final Rule published on September 30, 2016. In making the revisions, consideration was given to minimize the burden of the collection of information on respondents. The revised document contains revisions to improve the accuracy and clarity of policy questions, definitions, and guidance in order to improve the quality of information that is collected.

Consistent with the statute and regulations, ACF requests revisions of the ACF–118A to align with the requirements of the CCDF Final Rule.

Respondents: Tribal CCDF Lead Agencies (260).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF—118A Part I (for all tribes)	260	0.33	120	15,420
ACF—118A Part II (for medium and large allocation tribes only)	106	0.33	144	5,037

Estimated Total Annual Burden Hours: 20,457.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), 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.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–00386 Filed 1–30–19; 8:45 am]

BILLING CODE 4184–81–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0049]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

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 reporting harmful and potentially harmful constituents (HPHCs).

DATES: Submit either electronic or written comments on the collection of information by April 1, 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 April 1, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 1, 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–2012–D–0049 for ''Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act.'' 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: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0732—Extension

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act), enacted on June 22, 2009, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provided FDA with the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))).

In accordance with that authority, on May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority (final deeming rule) (81 FR 28974).

Chapter IX of the FD&C Act now applies to newly regulated products, including sections 904(a)(3) and (c)(1) (21 U.S.C. 387d(a)(3) and (c)(1)). Section 904(a)(3) of the FD&C Act requires the submission of an initial report from each tobacco product manufacturer or importer, or agents thereof, listing all constituents, including smoke constituents as applicable, identified as HPHC to health by FDA. Reports must be by brand and by quantity in each brand and subbrand. We note that for cigarettes, smokeless tobacco, cigarette

filler, and RYO tobacco products, this initial reporting was completed in 2012.

Section 904(c)(1) of the FD&C Act provides that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide the information reportable under section 904(a)(3) at least 90 days prior to introducing the product into interstate commerce.[1]

FDA has taken several steps to identify HPHCs to be reported under section 904 of the FD&C Act, including issuing a guidance discussing FDA's current thinking on the meaning of the term ''harmful and potentially harmful constituent'' in the context of implementing the HPHC list requirement under section 904(e) of the FD&C Act (76 FR 5387, January 31, 2011, revised guidance issued August 2016). The guidance is available on the internet at *https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm241339.htm.* The current established list of HPHCs also is available on the internet at *https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM297828.pdf* (77 FR 20034, April 3, 2012).

The purpose of the information collection is to collect statutorily mandated information regarding HPHCs in tobacco products and tobacco smoke, by brand and by quantity in each brand and subbrand.

To facilitate the submission of HPHC information, Forms FDA 3787a, 3787b, and 3787c for cigarettes, smokeless tobacco products, and RYO tobacco products, respectively, in both paper and electronic formats, are available. Additionally, FDA is developing forms to facilitate the submission of HPHC information for the newly deemed tobacco products. We intend to model these forms on the current HPHC reporting forms (*i.e.,* Forms FDA 3787a, 3787b, and 3787c). A proposed information collection for newly deemed products will be published in a separate **Federal Register** notice, and we will solicit comments on that collection at that time.

Manufacturers or importers, or their agents, may submit HPHC information either electronically or in paper format. The FDA eSubmitter tool provides electronic forms to streamline the data entry and submission process for reporting HPHCs for cigarettes, smokeless tobacco products, and RYO tobacco products. Users of eSubmitter may populate an FDA-created Excel file and import data into eSubmitter. Whether respondents decide to submit reports electronically or on paper, each form provides instructions for completing and submitting HPHC information to FDA. The forms contain fields for company information, product information, and HPHC information.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reporting for Section 904(c)(1) Products					
1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms					
Cigarette	67	0.67	45	1.82	82
RYO	46	0.033	1.5	0.43	1
Smokeless	42	0.54	23	0.63	14
Total					97
2. Testing of HPHC Quantities in Products					
Cigarette Filler and RYO	46	0.033	1.5	9.42	14
Smokeless	42	0.54	23	12.06	277
Total					291
3. Testing of HPHC Quantities in Mainstream Smoke					
Cigarette: ISO Regimen	67	0.67	45	23.64	1,064
Cigarette: Health Canada Regimen	67	0.67	45	23.64	1,064
Total					2,128
Total Section 904(c)(1) Reporting Burden Hours					2,516

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

The burden for this collection of information is estimated to be 2,516 hours. The burden estimate for this collection of information includes the time it will take to read the instructions, test the products, and prepare the HPHC report.

In arriving at this burden estimate, FDA estimated the number of tobacco products to be reported under the requirements of section 904(c)(1) of the FD&C Act annually to FDA.

Section 1 of table 1 estimates that 155 respondents (67 cigarette manufacturers or importers, 46 RYO tobacco manufacturers, 42 smokeless manufacturers) will submit 97 HPHC reports annually. This section addresses the time required for manufacturers and importers (or their agents), who must report their product information to FDA

[1] Note that section 904(c)(1) testing and reporting requirements are separate from the requirements that must be satisfied before a new tobacco product (sections 905 and 910 of the FD&C Act (21 U.S.C. 387e and 387j)), or modified risk tobacco product (section 911 of the FD&C Act (21 U.S.C. 387k)) may be marketed.

under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce for all new products, to report their company information to FDA through the use of the electronic portal or paper forms.

The company information reported includes: Company name; mailing address; telephone and Fax numbers; FDA Establishment Identifier number; Data Universal Numbering System number; and point of contact name, mailing address, and telephone and Fax numbers, as applicable. It also addresses the time required for manufacturers and importers to report their product information by entering certain testing information into the electronic or paper forms.

The product information includes: Brand and subbrand name; unique product identification number; type of product identification number; product category and subcategory; and mean weight and standard deviation of tobacco in product.

We estimate that the burden to enter both the company and product information is no more than 1.82 hours for cigarettes, 0.43 hours for RYO, and 0.63 hours for smokeless tobacco products regardless of whether the paper or electronic Form FDA series 3787 is used. The time to report per tobacco product types varies because the number of HPHCs varies by tobacco product category.

The estimated number of responses under section 904(c)(1) is based on FDA's experience and the past 3 years' actual responses to FDA under this provision of the FD&C Act for statutorily regulated products.

Section 2 of table 1 estimates that 88 respondents (46 cigarette filler and RYO tobacco manufacturers and importers and 42 smokeless manufacturers) will test quantities of HPHCs in an average of 24.5 products annually. This section addresses the time required for manufacturers and importers (or their agents) who must test HPHC quantities in products. The burden estimates include the burden to test the tobacco products, draft testing reports, and submit the report to FDA. The total expected burden for this section is 291 hours.

Section 3 of table 1 addresses the time required for manufacturers and importers to test quantities for HPHCs in cigarette smoke. The burden estimates include: The burden to test the number of replicate measurements; test date range; manufacture date range; extraction method; separation method; detection method; and mean quantity and standard deviation of HPHCs and includes the burden to test the tobacco products, draft testing reports, and submit the report to FDA. The annual burden reflects our estimate of the time it takes to test the tobacco products (*i.e.,* carry out laboratory work). The burden estimate assumes that manufacturers and importers report HPHC quantities in cigarette mainstream smoke according to the two smoking regimens. The total expected burden is 2,128 hours for this section.

The total estimated burden for this information collection is 2,516 hours and 139 responses.

Our estimated burden for the information collection reflects an overall decrease of 2,125 hours and a corresponding decrease of 142 responses. We attribute this decrease to updated information on the number of submissions we received over the last few years.

Dated: January 11, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–00448 Filed 1–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0070]

Microbiology Devices Panel Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Microbiology Devices Panel. 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 March 8, 2019, from 8 a.m. to 5 p.m.

ADDRESSES: Hilton Washington, DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's phone number is 301–977–8900; additional information available online at: *https://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-north-gaithersburg-GAIGHHF/index.html.* 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: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G642, Silver Spring, MD 20993–0002, *Aden.Asefa@fda.hhs.gov,* 301–796–0400, 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 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: On March 8, 2019, the committee will discuss and make recommendations regarding new or alternative approaches to the clinical study design and evaluation of devices detecting Human Papillomavirus (HPV) nucleic acid. These approaches will take into consideration scientific data generated since the approval of the first High Risk (HR) HPV screening device in 2003 as well as the effects of HPV vaccination on clinical studies of devices for HPV detection. Topics to be addressed at the meeting include clinical study design and comparator methods. Additionally, the committee will discuss potential changes to the HR HPV device indications for use considering continually evolving cervical cancer screening guidelines. The committee will provide expert feedback regarding the benefits and risks from the adoption of changes in each of the above topics and make recommendations for future HR HPV device evaluation strategies that are both scientifically rigorous and least burdensome.

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/*