Washington, DC 20201. Additional information is available at *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.*

SUPPLEMENTARY INFORMATION: The formation and operation of the NAC are governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of federal advisory committees.

Purpose of the NAC: The purpose of the NAC is to advise the Secretary and the Attorney General on practical and general policies concerning improvements to the nation's response to the sex trafficking of children and youth in the United States. The NAC is established pursuant to Section 121 of the Preventing Sex Trafficking and Strengthening Families Act of 2014 (Pub. L. 113–183).

Tentative Agenda: The agenda can be found at *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.*

To submit written statements or RSVP to attend, email *Ava.Donald@acf.hhs.gov* by January 2, 2019. Please include your name, organization, and phone number. More details on these options are below.

Public Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and subject to the availability of space, this meeting is open to the public. Seating is on a first to arrive basis. Security screening and a photo ID are required. The building is fully accessible to individuals with disabilities. Note: The January 9, 2019 meeting will only be held virtually.

Written Comments or Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the FACA, the public or interested organizations may submit written comments or statements to the NAC in response to the stated agenda of the meeting or in regard to the committee's mission in general. Organizations with recommendations on best practices are encouraged to submit their comments or resources (hyperlinks preferred). Written comments or statements received after January 2, 2019 may not be provided to the Committee until its next meeting.

Verbal Comments or Statements: Pursuant to 41 CFR 102–3.140d, the Committee is not obligated to allow a member of the public to speak or otherwise address the Committee during the meeting. Members of the public are invited to provide verbal statements during the Committee meeting only at the time and manner described in the agenda. The request to speak should include a brief statement of the subject matter to be addressed and should be relevant to the stated agenda of the meeting or the Committee's mission in general.

Minutes: The minutes of this meeting will be available for public review and copying within 90 days at: *https://www.acf.hhs.gov/otip/partnerships/the-national-advisory-committee.*

Dated: December 20, 2018.

Lynn A. Johnson,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2018–28264 Filed 12–27–18; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0536]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601

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 Form FDA 3601, entitled ''Medical Device User Fee Cover Sheet,'' which must be submitted along with certain medical device product applications, supplements, and fee payment of those applications.

DATES: Submit either electronic or written comments on the collection of information by February 26, 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 February 26, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 26, 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–N–0536 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601.'' 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.

Medical Device User Fee Cover Sheet, Form FDA 3601

OMB Control Number 0910–0511—Extension

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), and the Medical Device User Fee Amendments of 2007 (title II of the Food and Drug Administration Amendments Act of 2007), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the ''Medical Device User Fee Cover Sheet,'' is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research to initiate the administrative screening of new medical device applications and supplemental applications.

The total number of annual responses is based on the average number of cover sheet submissions received by FDA in recent years. The number of received annual responses includes cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates (18 minutes).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3601	6,379	1	6,379	0.30 (18 minutes)	1,914

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

Our estimated burden for the information collection reflects an overall increase of 350 hours and a corresponding increase of 1,165 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: December 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–28220 Filed 12–27–18; 8:45 am]

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