Estimated Total Annual Burden Hours: 11,163.

Authority: Section 426 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, 42 U.S.C.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–11312 Filed 5–26–20; 8:45 am]

BILLING CODE 4184–PC–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Office of Refugee Resettlement Unaccompanied Refugee Minors Program Application and Withdrawal of Application or Declination of Placement Form (Previous OMB #0970–0498)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR) is requesting a 3-year extension of the application and Withdrawal of Application or Declination of Placement Form for the Unaccompanied Refugee Minors (URM) Program. Proposed revisions to each instrument are minimal. These forms were previously approved under OMB #0970–0498, expiration 7/31/2020. ORR is currently seeking a new OMB number specific to these forms, as they were previously approved as part of another information collection package for ORR's Unaccompanied Alien Children's program.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The URM Program Application is completed on behalf of unaccompanied children in the United States who are applying for entry into the URM Program. The application includes biographical data and information on the child's needs to support placement efforts. The Withdrawal of Application or Declination of Placement Form is completed when a child is no longer interested in entering the URM program.

Respondents: Case managers, attorneys, or other representatives working with unaccompanied children who are eligible for the URM Program.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Unaccompanied Refugee Minors Program Application ...	350	3	1.50	1,575	525
Withdrawal of Application or Declination of Placement Form	30	3	0.20	18	6

Estimated Total Annual Burden Hours: 531.

Authority: 8 U.S.C. 1522(d).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–11307 Filed 5–26–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1875]

Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is hosting a virtual public meeting entitled ''Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments,'' and an opportunity for public comment. This public meeting will take place virtually due to extenuating circumstances and will be held by webcast only.

DATES: The public meeting will take place remotely on June 22, 2020, from 9 a.m. to 11 a.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

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 July 22, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 22, 2020. 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–2019–N–1875 for ''Financial Transparency and Efficiency of Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner, 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Monica Ellerbe, Office of Finance, Budget and Acquisitions, 4041 Powder Mill Rd., Rm. 72044, Beltsville, MD 20750, 301–796–5276, *Monica.Ellerbe@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The public meeting will include presentations from FDA on: (1) The 5-year plans for the Prescription Drug User Fee Act (PDUFA) VI, Biosimilar User Fee Act (BsUFA) II, and Generic Drug User Fee Amendments (GDUFA) II; (2) the Agency's progress in implementing resource capacity planning and modernized time reporting; and (3) the Agency's progress in addressing the findings from the independent third party evaluation of the resource management associated with PDUFA, BsUFA, and GDUFA that concluded and was published in fiscal year (FY) 2019. This meeting is intended to satisfy FDA's commitment to host an annual public meeting in the third quarter of each fiscal year beginning in FY 2019 and can be found in the Commitment letters listed below (II.B.3 of PDUFA VI (p. 38), IV.B.3 of BsUFA II (p. 28), and VI.B.4 of GDUFA II (p.22)).

This public meeting is intended to meet performance commitments included in PDUFA VI, BsUFA II, and GDUFA II. These user fee programs were reauthorized as part of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) signed by the President on August 18, 2017. The complete set of performance goals for each program are available at:

- PDUFA VI program: *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf;*
- BsUFA II program: *https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf;* and
- GDUFA II program: *https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf.*

Each of these user fee programs included a set of commitments related to financial management. These included commitments to publish a 5-year financial plan that should be updated annually, develop resource capacity planning capability and to modernize time reporting practices, and have a third-party evaluation of resource management practices for these user fee programs. In addition, each user fee program includes a commitment to host a public meeting in the third quarter of each fiscal year, beginning in FY 2019, to discuss specific topics.

II. Topics for Discussion at the Public Meeting

This public meeting will provide FDA the opportunity to update interested public stakeholders on topics related to the financial management of PDUFA VI, BsUFA II, and GDUFA II. FDA will present the 5-year financial plans for each of these programs and update participants on the progress towards implementing resource capacity planning and modernizing its time reporting approach. In addition, FDA will provide an update on the Agency's progress in addressing the findings from the independent third party evaluation of the resource management associated with PDUFA, BsUFA, and GDUFA that concluded and was published in FY 2019. To view the evaluation assessment report, please visit here: *https://www.fda.gov/media/127605/download.*

III. Attending the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://www.eventbrite.com/e/public-meeting-financial-transparency-and-efficiency-of-user-fee-programs-registration-101672491158.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this public meeting must register by June 19, 2020, at 11:59 p.m. Eastern Time. Registrants will receive confirmation once they have been accepted. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Monica Ellerbe no later than June 15, 2020, 11:59 p.m. Eastern Time.

Streaming Webcast of the Public Meeting: The webcast for this public meeting is *https://collaboration.fda.gov/fdafinancial062220/.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/*

help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 20, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11306 Filed 5–26–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1301]

Q3C(R8) Recommendations for the Permitted Daily Exposures for Three Solvents—2-Methyltetrahydrofuran, Cyclopentyl Methyl Ether, and Tert-Butyl Alcohol—According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; International Council for Harmonisation; Draft 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 draft recommendations for new permitted daily exposures (PDEs) for the residual solvents 2-methyltetrahydrofuran, cyclopentyl methyl ether, and tert-butyl alcohol. The PDEs were developed according to the methods for establishing exposure limits included in the guidance for industry entitled ''Q3C Impurities: Residual Solvents.'' The recommendations were prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance is intended to recommend acceptable amounts for the listed residual solvents in pharmaceuticals for the safety of patients.

DATES: Submit either electronic or written comments on the draft guidance by July 26, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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:

- *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–2020–D–1301 for ''Q3C(R8) Recommendations for the Permitted Daily Exposures for Three Solvents—2-Methyltetrahydrofuran, Cyclopentyl Methyl Ether, and Tert-Butyl Alcohol—According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents.'' Received comments 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.govinfo.gov/content/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–