

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Trafficking Victim Assistance Program Data Collection (OMB #0970-0467)

AGENCY: Office on Trafficking in Persons; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting to reinstate a previously approved information collection with revisions to information collected on clients enrolled in the Trafficking Victim Assistance Grant 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 directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov*. Alternatively, copies can also be obtained 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. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OTIP awards cooperative agreements for grantees to provide case management services to foreign national victims of a severe form of trafficking in persons who have received or are actively pursuing HHS Certification or Eligibility and their qualified family members (e.g., minor dependent children of victims or family members with derivative T visas), as authorized in the Trafficking Victims Protection Act of 2000 (22 U.S.C. 7105(b)(1)(B)).

Grantees provide services to qualified persons through a national network of subrecipient organizations.

OTIP proposes to collect information to measure grant project performance, provide technical assistance to grantees, assess program outcomes, improve program evaluation, respond to congressional inquiries and mandated reports, and inform policy and program development that is responsive to the needs of victims.

The information collection captures information on participant demographics (e.g., age, sex, and country of origin), types of trafficking experienced (sex, labor, or both), types of client enrollment, types of services and benefits provided along with aggregate information on the amount of money spent on each type of service provided, the types of entities providing medical services, the amount of money provided to those entities, the amount of money expended on each type of client enrollment, types of partnerships developed through the grant with subrecipients, and the types of training and technical assistance provided to subrecipient organizations or other partners.

Respondents: Trafficking Victim Assistance Program Grantees.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Annual burden hours |
|--|-----------------------------|------------------------------|------------------------------------|-----------------------------------|---------------------|
| Client Characteristics and Enrollment Form | 3,300 | 1,100 | 1 | 1 | 1,100 |
| Client Service Use and Delivery Form | 3,300 | 1,100 | 1 | .25 | 275 |
| Client Case Closure Form | 3,300 | 1,100 | 1 | .167 | 183.7 |
| Barriers to Service Delivery and Monitoring Form | 261 | 261 | 15 | .167 | 217.935 |
| TVAP Spending Form | 261 | 261 | 3 | .75 | 195.75 |
| Partnership Development Enrollment Form | 1 | 1 | 261 | .25 | 21.75 |
| Partnership Development Exit form | 1 | 1 | 261 | .083 | 7.221 |
| Training Form | 1 | 1 | 12 | .5 | 2 |
| Technical Assistance Form | 1 | 1 | 12 | .5 | 2 |

Estimated Total Annual Burden Hours: 2,005.

Authority: 22 U.S.C. 7105.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019-21759 Filed 10-4-19; 8:45 am]

BILLING CODE 4184-47-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-4284]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee

meeting of the Endocrinologic and Metabolic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 13, 2019, from 8 a.m. to 5 p.m.

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

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2019-N-4284. The docket will close on November 12, 2019. Submit either electronic or written comments on this public meeting by November 12, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 12, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 12, 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.

Comments received on or before October 29, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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-2019-N-4284 for "Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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." FDA 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 the 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:

LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: EMDAC@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 FDA'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: The committee will discuss supplemental new drug application (sNDA) 204629/S-020 for empagliflozin oral tablet, sponsored by Boehringer Ingelheim Pharmaceuticals, Inc., for the following proposed indication: As an adjunct to insulin therapy to improve glycemic control in adults with type 1 diabetes mellitus.

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/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. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 29, 2019, will be provided to

the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 October 21, 2019. 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 October 22, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaoama@fda.hhs.gov or 301-796-4540.

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 LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website 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 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.
[FR Doc. 2019-21834 Filed 10-4-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3500]

Fit for Use Pilot Program Invitation for the Clinical Data Interchange Standards Consortium for Standard for Exchange of Nonclinical Data Implementation Guide: Version 3.1; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Tuesday, August 20, 2019. The document announced a "Fit for Use Pilot Program Invitation for the Clinical Data Interchange Standards Consortium for Standard for Exchange of Nonclinical Data Implementation Guide: Version 3.1." The document was published with the incorrect contact name, phone number, and email address in the **FOR FURTHER INFORMATION CONTACT** section. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT:

Jesse Anderson, Office of Computational Science, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-348-1816, Jesse.Anderson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In FR Doc. 2019-17877, appearing on page 43139, in the **Federal Register** of Tuesday, August 20, 2019 (84 FR 43139), the following correction is made:

On page 43140, in the first column, in the **FOR FURTHER INFORMATION CONTACT** section of the document, "Isaac Chang, Office of Computational Science, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240-4027501, PRAStaff@fda.hhs.gov." is corrected to read "Jesse Anderson, Office of Computational Science, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-348-1816, Jesse.Anderson@fda.hhs.gov."

Dated: September 30, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.
[FR Doc. 2019-21784 Filed 10-4-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0477]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational Device Exemptions Reports and Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 6, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0078. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10a.m.-12p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Investigational Device Exemptions Reports and Records

OMB Control Number 0910-0078—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-