occasional graduate-level interns. Since its inception in June 2015, OTIP's responsibilities have expanded exponentially driven by new statutory requirements, increased appropriations, Executive Order directives, Administration-driven priorities, and emerging issues in the anti-trafficking field that have necessitated an increase in inter- and intra-agency collaboration.

The changes announced herein describe the restructuring of OTIP within the Office of the Assistant Secretary for Children and Families, ACF, into three divisions—Prevention, Protection, and Research and Policy—that report to the OTIP Director.

I. Under Chapter KA.20, the Office on Trafficking in Persons Makes the Following Changes

KA.10 E. Organization. The Office on Trafficking in Persons (KAI): OTIP has the following three strategic goals: Establish a cohesive national human trafficking victim service delivery system; develop a culture of data-informed anti-trafficking programming and policymaking; and integrate survivor-informed anti-trafficking efforts into HHS prevention strategies. OTIP implements numerous legislatively mandated programs and policies to combat human trafficking. OTIP's activities are authorized by federal statutes including, but not limited to, the Trafficking Victims Protection Act, as amended and reauthorized; the Justice for Victims of Trafficking Act; the Preventing Sex Trafficking and Strengthening Families Act; the Frederick Douglass Trafficking Victims Prevention and Protection Reauthorization Act; and the Stop, Observe, Ask, and Respond to Health and Wellness Act (or the SOAR to Health and Wellness Act).

The OTIP Director reports to the Assistant Secretary, ACF. The Director provides strategic leadership and direction on anti-trafficking programs and policies, anti-trafficking prevention efforts, building health and human service capacity to respond to human trafficking, strategies to increase victim identification and access to services, and strengthen the long-term health and well-being outcomes of survivors of human trafficking. OTIP is responsible for the overall leadership of anti-trafficking programs and services under the purview of ACF, including, but not limited to, developing and implementing programs that assist both foreign and domestic victims of human trafficking as well as implementing anti-trafficking statutory, appropriations, and Administration-driven priorities.

OTIP has the following three divisions: Protection (victim assistance), Prevention (capacity building, prevention, and public awareness), and Research and Policy. A description of each of the proposed divisions follows.

Protection Division

The Protection Division is comprised of OTIP's victim service and assistance activities. It includes the Trafficking Victim Assistance Program, the Domestic Victims of Human Trafficking Programs, the Child Eligibility and Adult Certification programs, Child Victim Coordination Activities, and the National Human Trafficking Hotline. Through a combination of grant activities and internal direct services, OTIP assists adult and minor, foreign and domestic victims of severe forms of trafficking in persons and participates in intra- and inter-agency coordination efforts to inform anti-trafficking program and policy development to improve our response to victims and efficiency in federally supported programming.

Prevention Division

The Prevention Division develops cutting-edge training and technical assistance, promotes survivor engagement, raises public awareness, facilitates regional outreach and coordination, and disseminates prevention education resources with the ultimate goal of assisting communities and programs in building capacity to effectively identify victims, implement trafficking prevention efforts, and coordinate education and outreach efforts. The Division oversees the National Human Trafficking Training and Technical Assistance Center, prevention education programming and the National Prevention Action Plan, the SOAR to Health and Wellness program, and the Look Beneath the Surface Public Awareness Campaign and Communication that includes OTIP's website content and conference and meeting planning and representation.

Research and Policy Division

The Research and Policy Division is responsible for the identification, coordination, and implementation of the anti-trafficking research agenda and policy development activities. The Division coordinates program evaluation and research, prepares documentation to comply with regulatory requirements, reviews and analyzes proposed legislation, develops and tracks program performance metrics, represents OTIP at internal and external data and policy events, provides technical support for data collection efforts, guides the development of program information systems, prepares annual and ad hoc reports and informational materials, and ensures program development is evidence-based and theory-driven through research and evaluation efforts.

Linda K. Hitt,

Executive Secretariat Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2382]

Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs 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: Endpoints for Demonstrating Effectiveness of Drugs for Treatment.'' This guidance addresses clinical endpoints acceptable to demonstrate effectiveness of drugs for treatment of opioid use disorder. This guidance addresses comments received for and finalizes the draft guidance of the same name issued August 7, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on October 2, 2020.

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:

• *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–2018–D–2382 for ''Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Treatment.'' 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, 240–402–7500.

• 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, 240–402–7500.

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

Submit written requests for single copies of the 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Silvana Borges, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3200, Silver Spring, MD 20993–0002, 301–796–0963.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Treatment.'' This guidance addresses clinical endpoints acceptable to demonstrate effectiveness of drugs for treatment of opioid use disorder.

This guidance finalizes the draft guidance of the same name issued August 7, 2018 (83 FR 38699). All the public comments received on the draft guidance have been considered and the guidance has been revised as appropriate in response to such comments along with a few editorial changes.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Opioid Use Disorder: Endpoints for Demonstrating Effectiveness of Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: September 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21826 Filed 10–1–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0386]

Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs

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 information collection associated with Orphan Drug provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and implementing regulations.

DATES: Submit either electronic or written comments on the collection of information by December 1, 2020.

ADDRESSES: You may submit comments as follows. Please note that late,