Technical Assistance Center (NHTTAC) Evaluation Package (Office of Management and Budget (OMB) #0970–0519, expiration 03/31/2023). Items were expanded to include measures related to specific skills, competencies, and knowledge and outcomes at the organizational and community levels, and the annual burden has increased for several forms.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The NHTTAC delivers training and technical assistance (T/TA) to inform and deliver a public health response to trafficking. In applying a public health approach, NHTTAC holistically builds the capacity of professionals, organizations, and communities to identify and respond to the complex needs of all individuals who have experienced trafficking or who have increased risk factors for trafficking and address the root causes that put individuals, families, and communities at risk of trafficking. These efforts ultimately help improve the availability and delivery of coordinated and trauma-informed services before, during, and after an individual's trafficking exploitation, regardless of their age, gender identity, sexual orientation, race/ethnicity, nationality, or type of exploitation experienced.

NHTTAC hosts a variety of services, programs, and facilitated sessions to improve service provision to people who have experienced trafficking or who have increased risk factors for trafficking, including The Human Trafficking Leadership Academy; SOAR (Stop, Observe, Ask, and Respond) to Health and Wellness; OTIP-funded recipients; both short-term and specialized T/TA requests; the NHTTAC Customer Support; and information through NHTTAC's website, resources, and materials about trafficking. This information collection is intended to collect feedback from participants to assess a diverse range of T/TA provided by NHTTAC.

Revisions have been made in order to:

- Respond to Postgraduate Institute for Medicine accreditation requirements through SOAR T/TA
- Reduce burden where applicable
- Provide flexibility for NHTTAC to assess new knowledge gains, application of skills/competencies, and outcomes of participants who received NHTTAC T/TA
- Understand NHTTAC's progress on improving diversity, equity, and inclusion

Respondents: NHTTAC T/TA participants include OTIP grant recipients, individuals with lived experience, professionals who interact with and provide services to individuals who have experienced trafficking, including healthcare, behavioral health, public health, and human service practitioners, organizations, and communities.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Universal T/TA Participant Feedback—Long Version	2,100	1	0.43	903
Universal T/TA Participant Feedback—Short Version	50,000	1	0.10	5,000
Intensive T/TA Participant Feedback	650	1	1.17	761
Follow Up Feedback	10,000	1	0.50	5,000
Qualitative Guide	2,200	1	1.50	3,300
Network Survey	600	1	1.00	600
Client Satisfaction Survey	1,000	1	0.08	80
Resources Feedback	500	1	0.08	40
Requester Feedback	250	1	0.12	30

Estimated Total Annual Burden Hours: 15,714.

Authority: 22 U.S.C. 7104 and 22 U.S.C. 7105(c)(4).

John M. Sweet Jr,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–06097 Filed 3–23–23; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3319]

Framework for the Use of Digital Health Technologies in Drug and Biological Product Development; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the publication of a digital health technology (DHT) framework by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research. This framework is entitled ''Framework for the Use of Digital Health Technologies in Drug and Biological Product Development.'' This fulfills an FDA commitment under the seventh iteration of the Prescription Drug User Fee Act (PDUFA VII) reauthorization, incorporated as part of the FDA User Fee Reauthorization Act of 2022.

DATES: Either electronic or written comments on the framework must be submitted by May 23, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 23, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2022–N–3319 for ''Framework for the Use of Digital Health Technologies in Drug and Biological Product Development.'' 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, 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.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: Ryan Robinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3342, Silver Spring, MD 20993–0002, 240–402–9756, *Ryan.Robinson1@fda.hhs.gov;* or Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In connection with PDUFA VII, incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to establish a framework that will guide the use of DHT-derived data in regulatory decision-making for drug and biological products. FDA is publishing the ''Framework for the Use of Digital Health Technologies in Drug and Biological Product Development'' to satisfy the PDUFA VII commitment.

DHTs may provide opportunities for more efficient drug development. DHTs and DHT-derived data can be important tools in supporting timely access to safe, effective, and innovative new medicines for patients. Despite the potential advantages of DHTs, many challenges arise when incorporating DHTs and DHT-derived data into regulatory decision-making. This framework outlines a multifaceted approach to collaboratively address these challenges with stakeholders. Through these joint efforts, FDA intends to advance the development of drugs and promote the public health.

The framework will guide activities such as (1) defining objectives for workshops and demonstration projects, (2) developing methodologies for evaluating DHTs proposed as measuring key (primary or important secondary) endpoints or other important measures (*e.g.,* for safety monitoring or baseline characterization) in clinical trials, (3) managing submissions with extensive and continuous data (*e.g.,* in order to develop acceptable approaches to capture adverse events), and (4) developing a standardized process for data management and analysis of large datasets from DHTs.

II. Electronic Access

Persons with access to the internet may obtain the ''Framework for the Use of Digital Health Technologies in Drug and Biological Product Development'' at *https://www.fda.gov/science-research/science-and-research-special-topics/digital-health-technologies-dhts-drug-development.*

Dated: March 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06066 Filed 3–23–23; 8:45 am]

BILLING CODE 4164–01–P