DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Request for Certification of Adult Victims of Human Trafficking

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

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office on Trafficking in Persons (OTIP), is requesting a 3-year extension of the Request for Certification of Adult Victims of Human Trafficking (RFC) form (Office of Management and Budget (OMB) #: 0970–0454, expiration 2/28/22). Minor revisions have been made to the form, including the addition of a few fields that will enable OTIP to be more responsive to congressional inquiries, federal reporting requirements, and the needs of victims.

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.* All emailed requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The U.S. Department of Health and Human Services (HHS) provides letters of certification to foreign national victims of severe forms of trafficking in persons under the authority of the Trafficking Victims Protection Act of 2000 (TVPA), as amended 22 U.S.C. Section 7105(b)(1)(C) and (E). HHS delegated this authority to OTIP. Certification is required for foreign national adult victims of human trafficking in the United States to apply for federally funded benefits and services.

OTIP developed a form for potential victims and their advocates, including case managers, attorneys, law enforcement officers, service providers, and other representatives to provide the required information for certification to HHS in accordance with the TVPA of 2000, as amended. The RFC form (formerly titled Trafficking Victims Tracking System) was renamed in order to create continuity between the RFC and Request for Assistance for Child Victims of Human Trafficking (RFA) forms (OMB Control Number 0970–0362).

Since the RFC form originally received clearance, OTIP modernized its request process and launched Shepherd, an online case management system, to process requests for certification and assistance on behalf of foreign national adult and minor victims of trafficking. The PDF version of the form should only be used in exceptional circumstances when the online case management system is inaccessible. If a requester encounters issues submitting a request through Shepherd, they may submit the RFC form to OTIP as a password protected PDF to *Trafficking@acf.hhs.gov.* The form asks the requester for their identifying information, identifying information for the foreign national adult in the event the form is submitted by a case manager, and information describing the victim's case management service needs. The minor revisions made to this form enable OTIP to better fulfill its mandate in accordance with the TVPA of 2000, as amended. These revisions also enable OTIP to be more responsive to congressional inquiries, federal reporting requirements, and the needs of victims, as the information provided will be factored into policy and program development efforts.

Respondents: Potential victims of a severe form of trafficking in persons and their advocates, including case managers, attorneys, law enforcement officers, service providers, and other representatives.

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
Request for Certification of Adult Victims of Human Trafficking	1,300	1	1	1,300	433

Estimated Total Annual Burden Hours: 433.

Authority: 22 U.S.C. 7105.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–01524 Filed 1–25–22; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1564]

Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation; Guidance for Industry and Food and Drug Administration Staff, and Other Stakeholders; 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 entitled ''Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation.'' FDA encourages the collection, analysis, and integration of patient perspectives in the development, evaluation, and surveillance of medical devices, including digital health technologies. Patient-reported outcome (PRO) instruments facilitate the systematic

collection of patient perspectives as valid scientific evidence to support the regulatory and healthcare decision-making process. This guidance describes principles that should be considered when using PRO instruments in the evaluation of medical devices and provides recommendations about the importance of ensuring the measures are fit-for-purpose. This guidance is not meant to replace the Patient-Focused Drug Development (PFDD) guidance series. Some of the comments received in the docket may be addressed in PFDD Guidance #3, which is currently in development.

DATES: The announcement of the guidance is published in the **Federal Register** on January 26, 2022.

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–2020–D–1564 for ''Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation.'' 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.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.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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 request.

FOR FURTHER INFORMATION CONTACT: Michelle Tarver, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5608, Silver Spring, MD 20993–0002, 301–796–6884; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

A PRO instrument can be used in a clinical investigation to measure the effects of a medical intervention or changes in the health status of a patient. PRO instruments allow for collection of certain data as valid scientific evidence of safety and effectiveness that is complementary to other clinical outcomes and/or biomarkers. Information from well-defined and reliable PRO instruments can provide valuable evidence for benefit-risk assessments and can be used in medical device labeling to communicate the effect of a treatment on patient symptoms, functioning, or quality of life when the labeling is consistent with the PRO instrument's documented measurement capability. PRO instruments may be used to inform a patient's eligibility for inclusion within a study, to capture safety or effectiveness outcomes, and may be aligned as primary or secondary endpoints or used as a stand-alone outcome assessment or component of a composite endpoint. When data from a PRO instrument is used in the evaluation of a medical device, FDA

determines the validity evidence needed to support the PRO instrument's specified use for a regulatory purpose. FDA uses the term ''fit-for-purpose'' to describe this flexible approach. As part of providing valid scientific evidence to assess the safety and effectiveness of medical devices, PRO instruments can measure the impact of medical devices on patient well-being and other concepts that may influence payers, healthcare providers, and patients when making decisions about potential treatments or management options.

A notice of availability of the draft guidance appeared in the **Federal Register** of August 31, 2020 (85 FR 53820). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarifying and expanding examples, making clear the language relating to PRO instrument scores, as well as clarifying the applicability of PRO instruments throughout the total product life cycle and within clinical studies. Additional language on recommendations to document modifications, ensure content is relevant, and consider patient burden was also included. This guidance is not meant to replace the Patient-Focused Drug Development (PFDD) guidance series. Comments received in the docket related to the PFDD guidance series have been shared with the Center for Drug Evaluation and Research (CDER) to be considered as part of the development of PFDD Guidance #3 entitled ''Selecting, Developing or Modifying Fit-for-Purpose Clinical Outcome Assessments'' and PFDD Guidance #4 entitled ''Incorporating Clinical Outcome Assessments into Endpoints for Regulatory Decision Making.'' [1]

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 ''Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation.'' 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 18042 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act''.	513(g) Request for Information	0910–0705
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: January 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01377 Filed 1–25–22; 8:45 am]

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[1] For more information, please see the FDA PFDD Guidance Series website: *https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical.*