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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Request for Assistance for Child 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 three-year extension of the form: Request for Assistance (RFA) for Child Victims of Human Trafficking (OMB #0970-0362, expiration 07/31/2021). Minor revisions have been made to the form, including the addition of a few fields that will enable the OTIP Child Protection Specialist team to better understand the child’s specific needs, connect the child to appropriate services, and help ensure the safety of the child.

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.

SUPPLEMENTARY INFORMATION:

Description: The Trafficking Victims Protection Act (TVPA) of 2000, as amended directs the Secretary of the U.S. Department of Health and Human Services (HHS), upon receipt of credible information that a foreign national minor may have been subjected to a severe form of trafficking in persons and is seeking assistance available to victims of trafficking, to promptly determine if the child is eligible for benefits and services to the same extent as refugees. HHS delegated this authority to the Office on Trafficking in Persons (OTIP).

OTIP developed a form for case managers, attorneys, law enforcement officers, child welfare workers, and other representatives to report these trafficking concerns to HHS in accordance with the TVPA of 2000, as amended, and allow for OTIP to review the concerns and determine eligibility for benefits.

Specifically, the form asks the requester for their identifying information, identifying information for the child, and information describing the potential trafficking concerns. The form takes into consideration the need to compile information regarding a child’s experiences in a trauma-

informed and child-centered manner and assists the requester in assessing whether the child may have been subjected to a severe form of trafficking in persons. The information provided through the completion of a Request for Assistance (RFA) for Child Victims of Human Trafficking form enables OTIP to make prompt determinations regarding a foreign national minor’s eligibility for assistance, facilitate the required consultation process should the minor receive interim assistance, and enable OTIP to assess and address potential child protection issues. OTIP also uses the information provided to respond to congressional inquiries, fulfill federal reporting requirements, and inform policy and program development that is responsive to the needs of victims.

In 2019, OTIP launched Shepherd, an online case management system, to process requests for assistance and certification on behalf of foreign national minor and adult victims of trafficking. If a requester encounters issues submitting a request through Shepherd, they may submit the RFA form to OTIP as a password protected PDF to childtrafficking@acf.hhs.gov.

Respondents: Representatives of governmental entities, members of the community, and nongovernmental entities providing social, legal, or protective services to foreign national minors in the United States who may have been subjected to severe forms of trafficking in persons. Furthermore, representatives within the community with a concern that a foreign national minor may have been subjected to severe forms of trafficking in persons may also use the RFA form.

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 Assistance for Child Victims of Human Trafficking	1,200	1	1	1,200	400

Estimated Total Annual Burden Hours: 400.

Authority: 22 U.S.C. 7105(b).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1853]

Unique Device Identification System: Form and Content of the Unique Device Identifier; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance entitled “Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI).” This document describes the requirements for, and FDA’s recommendations regarding, the form and content of the UDI to help ensure that the UDIs developed under systems for the issuance of UDIs meet the objectives of the Unique Device Identification System Final Rule.

DATES: The announcement of the guidance is published in the **Federal Register** on July 7, 2021.

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-2016-D-1853 for “Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI).” 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 “Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT:

Christopher Diamant, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3210, Silver Spring, MD 20993-0002, 301-796-5995 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

This document is intended to assist labelers, as defined in 21 CFR 801.3, and FDA-accredited issuing agencies, as defined in 21 CFR 830.3, in complying with UDI labeling requirements, including by clarifying FDA’s interpretation of certain requirements under 21 CFR 801.40. Specifically, this guidance describes the requirements for, and FDA’s recommendations regarding, the form and content of the UDI to help ensure that the UDIs developed under systems for the issuance of UDIs meet the objectives of the Unique Device Identification System Final Rule, 78 FR