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

Increased awareness of reporting requirements under the TVPA of 2000, as amended among providers who serve foreign national children and youth has resulted in sustained, year-over-year increases in the number of RFA forms received by OTIP since fiscal year 2021. While the number of RFA forms received by OTIP each year largely reflects OTIP's efforts to engage case managers, attorneys, law enforcement officers, child welfare workers, and other representatives who serve foreign national children and youth, the number of RFA forms received is also impacted by a variety of social, political, and environmental factors that impact migration trends, including natural disasters and other climate-mediated events, that fluctuate each year. In fiscal year 2021, a record number of unique individuals (2,178) were referred to OTIP through 2,650 total RFA forms. In fiscal year 2022, 3,150 unique individuals were referred to OTIP through 3,709 total RFA forms. In fiscal year 2023, 3,612 unique individuals were referred to OTIP through 4,052 total RFA forms. There are no changes proposed to the RFA form but based on the increased need for trafficking-specific case management services among foreign national children and youth, as evidenced through sustained increases in the volume of RFA forms received by OTIP each year since fiscal year 2021, burden estimates for this collection have been revised.

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	10,500	1	1	10,500	3,500

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

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–15789 Filed 7–17–24; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0113]

Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies; 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 ''Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies.'' This guidance describes FDA's recommendations regarding clinical pharmacology considerations for conducting human radiolabeled mass balance studies, including deciding whether and when to conduct the study, designing the study, and reporting results.

DATES: The announcement of the guidance is published in the **Federal Register** on July 18, 2024.

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–2022–D–0113 for ''Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies.'' 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)).

Submit written requests for single copies of this 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: Anuradha Ramamoorthy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, *Anuradha.ramamoorthy@fda.hhs.gov,* 240–402–6426.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies.'' A human radiolabeled mass balance study is the single most direct study to obtain quantitative and comprehensive information on the absorption, distribution, metabolism, and excretion of an investigational drug in the human body. The mass balance study can provide information to determine the overall pathways of metabolism and excretion of an investigational drug, identify circulating metabolites, and determine the abundance of metabolites relative to the parent or total drug-related exposure. This guidance provides FDA's recommendations for clinical pharmacology considerations in conducting human radiolabeled mass balance studies during drug development, including: (1) deciding whether and when to conduct the study, (2) designing the study, and (3) reporting the study results.

This guidance finalizes the draft guidance of the same name issued on May 5, 2022 (87 FR 26763). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) updates to terms used in the guidance to provide clarity, (2) additional references that have been published since the draft guidance was issued, and (3) editorial changes to improve clarity.

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 ''Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 201.57 relating to prescription product labeling requirements have been approved under OMB control number 0910–0572. The collections of information for submission of investigational new drug applications in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information for submission of new drug applications in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

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

Dated: July 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15812 Filed 7–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 8W–25A, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking