Recipient	Award amount
Partnership for Trauma Recovery, Berkeley, California	30,000
Program for Torture Victims LA County, Los Angeles, California	20,000
The Center for Victims of Torture, Atlanta, Georgia	$3,000
The Center for Victims of Torture, St. Paul, Minnesota	70,000

These programs will provide direct services to the 222 Nicaraguan Humanitarian Parolees (NHP) who were released from prison in Nicaragua and brought to the United States by the U.S. Department of State in February 2023.

On February 16, 2023, ORR issued Dear Colleague Letter 23–16, which stated that while the NHP's current immigration status does not provide eligibility for refugee program assistance, they may apply for assistance from ORR-funded Survivors of Torture (SOT) grant recipients. ORR has been working closely with the U.S. Department of State to connect these individuals to SOT grant recipients and other local service providers. Due to the nature and length of the NHP's detention in Nicaragua, their sudden release from prison and entry into the United States, and their temporary immigration status, these individuals need immediate assistance. The SOT grant recipients identified above are willing to provide medical, mental health, case management, and legal services to these individuals. However, the timing of these arrivals and the concentration in certain states has overwhelmed the capacity of SOT grant recipients in these locations. The supplemental awards will enhance the grant recipients' capacity to provide essential care and support for NHP so that they can begin the healing process.

Statutory Authority: Section 5(a) of the ''Torture Victims Relief Act of 1998,'' Public Law 105–320 (22 U.S.C. 2152 note) Assistance for Treatment of Torture Victims.

Karen D. Shields,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

[FR Doc. 2023–15650 Filed 7–24–23; 8:45 am]

BILLING CODE 4184–46–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0155]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods; Reopening of the Comment Period

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the notice entitled ''Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Quantitative Research on Front of Package Labeling on Packaged Foods,'' published in the **Federal Register** of June 15, 2023, to allow interested parties additional time to submit comments. We are taking this action due to technical difficulties experienced on the final two days of the comment period that may have prevented some interested parties from submitting comments.

DATES: FDA is reopening the comment period on the notice published on June 15, 2023 (88 FR 39257). Submit written comments (including recommendations) on the collection of information by 11:59 p.m. on Wednesday, July 26, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRA/icrPublicCommentRequest?ref_nbr=202306-0910-004*. You may also find this particular information collection at *https://www.reginfo.gov/public/do/PRAMain* by following these instructions: Under the header ''Currently under Review Select Agency'' use the drop down menu to select ''Department of Health and Human Services'' or by using the search function. The title of this information collection is ''Quantitative Research on Front of Package Labeling on Packaged Foods.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 15, 2023 (88 FR 39257), FDA announced that a proposed collection of information had been submitted to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. Interested parties were originally given until July 17, 2023, to submit comments (including recommendations) on the information collection.

However, on July 16 and 17, 2023, technical difficulties may have prevented some stakeholders from submitting electronic comments. Therefore, we are reopening the comment period to allow interested parties additional time to submit comments. The reopened comment period provides an opportunity for stakeholders who may have been impacted by the technical difficulties.

Dated: July 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15639 Filed 7–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–D–0055 and FDA–2020–N–1790]

M7(R2) Assessment and Control of Deoxyribonucleic Acid Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk, M7(R2) Addendum, and M7(R2) Questions and Answers; International Council for Harmonisation; Guidances 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 ''M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk'' (M7(R2) Guidance) and two supplemental documents entitled ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guidance to Calculation of Compound-Specific Acceptable Intakes'' (M7(R2) Addendum) and ''M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk Questions and Answers'' (M7(R2) Questions and Answers). The M7(R2) Guidance, M7(R2) Addendum, and M7(R2) Questions and Answers were prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The guidance and supplemental documents are intended to harmonize the considerations for assessment and control of DNA reactive (mutagenic) impurities. The M7(R2) Guidance and M7(R2) Addendum replace the guidance for industry entitled ''M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk,'' issued on March 14, 2018. The M7(R2) Guidance, M7(R2) Addendum, and M7(R2) Questions and Answers, also finalize the draft guidances for industry entitled ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes'' and ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk—Questions and Answers'' issued on April 7, 2022, and September 29, 2020, respectively.

DATES: The announcement of the guidance is published in the **Federal Register** on July 25, 2023.

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–0055 for ''M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk,'' and ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guidance to Calculation of Compound-Specific Acceptable Intakes,'' or Docket No. FDA–2020–N–1790 for ''M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk Questions and Answers.'' 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, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Aisar Atrakchi, Center for Drug Evaluation and Research, Food and Drug

Administration, 10904 New Hampshire Ave., Bldg. 22, Rm. 4118, Silver Spring, MD 20993–0003, 301–769–1036.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.'' The guidance was prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of April 7, 2022 (87 FR 20435), FDA published a notice announcing the availability of a draft guidance for industry entitled ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes,'' which included ICH assembly approved changes, including the separation of the main guidance and addendum into two separate documents. In the **Federal Register** of September 29, 2020 (85 FR 61009), FDA published a notice announcing the availability of a draft guidance for industry entitled ''M7 Assessment and Control of DNA reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk—Questions and Answers.'' The notices gave interested persons an opportunity to submit comments by May 9, 2022, and December 28, 2020, respectively.

After consideration of the comments received and revisions to the guidances, final drafts of the guidance and supplemental documents were submitted to the ICH Assembly and endorsed by the regulatory Agencies on May 24, 2022, and April 3, 2023.

These guidances finalize the above draft guidances issued on April 7, 2022, and September 29, 2020, with no significant changes. The M7(R2) Guidance is intended to be read in conjunction with two accompaniment documents, the M7(R2) Addendum and the M7(R2) Questions and Answers. The core M7(R2) Guidance includes information on mutagenic impurities and changes to HIV treatment duration. The M7(R2) Addendum contains monographs for mutagenic chemicals that are common in pharmaceutical manufacturing or are useful to illustrate the principles for deriving compound-specific intakes described in the core guidance. The M7(R2) Questions and Answers facilitate consistent implementation by clarifying issues and concerns identified since the first version of the final guidance for industry, ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk,'' published in 2014.

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 ''M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.'' 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 these guidances contains no collection of information, they do 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 these guidances. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information pertaining to 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice requirements have been approved under OMB control number 0910–0139.

III. Electronic Access

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

Dated: July 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15645 Filed 7–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.