reimbursed for the costs of providing these services and benefits for 4 months after an eligible recipient arrives in this country. The eligible beneficiaries for these services and benefits are refugees, Amerasians, Cuban and Haitian Entrants, asylees, Afghans and Iraqi with Special Immigrant Visas, victims of a severe form of trafficking, and other populations specified by Congress. States that provide services for unaccompanied refugee minors also provide an estimate for the cost of these services for the year for which they are applying for grants.

The proposed revisions include minor changes to the existing ORR–1 form and the addition of a template recipients must use in preparing their annual budget justification estimates in accordance with the refugee resettlement program regulations. Currently, recipients must submit the ORR–1, CMA Program Estimates, as the application for grants under the CMA program. A budget justification in support of CMA estimates must be submitted along with the ORR–1 form; however, ORR does not currently provide a standardized budget justification template. As a result, submissions vary widely in format, content, and level of detail, making it challenging to extract and standardize information, which increases the burden on both ORR reviewers and recipients. This revision to the information collection process requires states and Replacement Designees (RD) to submit budget justifications in a standardized format via a Microsoft Excel workbook, with each tab of the justification in alignment with a specific line on the ORR–1. The ORR–1 form has been updated with minor revisions, including updated column and line titles to reflect current terminology, and a simplified structure that replaces unit cost estimates with total cost estimates. These revisions are a result of the standardization of the budget justification.

The revised instructions, which are now embedded within the standardized budget justification, provide guidance to recipients on how to fill out each section of the standardized budget justification. The recipients work through corresponding sections of the instructions and budget justification, and the standardized format makes clear what information is needed and at what level of detail. Upon completion of the budget justification, the values needed to populate the ORR–1 form are automatically calculated, and recipients are instructed to transfer specific data from the budget justification to the ORR–1 form in the system of record.

ORR conducted a pilot of the standardized budget justification. Feedback was positive, with participating states citing time savings in development of their budget justification and more streamlined and consistent review and analysis by ORR reviewers. The annual burden estimate has been revised to reflect this.

Respondents: State Agencies, the District of Columbia, and Replacement Designees under 45 CFR 400.301(c) administering or supervising the administration of programs under Title IV of the Act.

ANNUAL BURDEN ESTIMATES

Information collection	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Total burden hours
ORR–1, CMA Program Estimates	57	1	0.5	28.5

Authority: 8 U.S.C. 1522(a)(4).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–11546 Filed 6–23–25; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–1106]

Q1 Stability Testing of Drug Substances and Drug Products; International Council for Harmonisation; Draft 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 draft guidance for industry entitled ''Q1 Stability Testing of Drug Substances and Drug Products.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance outlines stability data expectations for drug substances and drug products to support drug product marketing, including marketing authorization applications and, where applicable, drug master files. This draft guidance is a consolidated revision of the ICH Q1A(R2), Q1B, Q1C, Q1D, Q1E, and Q5C series of stability guidances, published November 2003, March 1996, May 1997, January 2003, June 2004, and July 1996, respectively. The revision also provides stability related guidance for product categories such as advanced therapy medicinal products, vaccines, and other complex biological products including combination products that were not previously covered under the existing stability guidances. The draft guidance is intended to provide an internationally harmonized approach to conducting and presenting data on stability testing for drug substances and drug products, as well as providing alternative, scientifically justified approaches that may be encountered due to scientific considerations and characteristics of the data being evaluated.

DATES: Submit either electronic or written comments on the draft guidance by August 25, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2025–D–1106 is for ''Q1 Stability Testing of Drug Substances and Drug Products.'' 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 the draft 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, 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 Center for Biologics Evaluation and Research at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Ee-Sunn Chia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 2550, Silver Spring, MD 20993–0002, 240–402–8909, email: *Ee-Sunn.Chia@fda.hhs.gov;* or Ramjay Vatsan Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6010, 240–402–8364, email: *ramjay.vatsan@fda.hhs.gov.*

Regarding the ICH: Brooke Dal Santo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993–0002, 301–348–1967, email: *Brooke.DalSanto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Q1 Stability Testing of Drug Substances and Drug Products.'' The draft 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 the 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 April 2025, the ICH Assembly endorsed the draft guideline entitled ''Q1 Stability Testing of Drug Substances and Drug Products'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be

considered by FDA and the Quality Expert Working Group.

The draft guidance provides recommendations on data expectations for drug substances and drug products to support marketed drug products including those with registration submissions, lifecycle/postapproval changes, and when applicable, master files. This draft guidance consolidates and updates the recommendations made in the ICH Q1A(R2), Q1B, Q1C, Q1D, Q1E, and Q5C series of stability guidances (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*), by addressing consistency of interpretation, clarification of technical components of stability concepts, recommendations for new technologies and tools used to facilitate an enhanced product understanding, and applicability of recommendations across the lifecycle of a product. This draft guidance can apply to all marketing authorization applications of prescription and nonprescription drugs (*e.g.,* new, abbreviated) for a broad range of drug substances and products (*e.g.,* chemically synthesized, therapeutic and well-characterized proteins and polypeptides, vaccines, cell and gene therapy, drug-device combinations, natural health products).

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''Q1 Stability Testing of Drug Substances and Drug Products'' and will supersede the ICH Q1A(R2), Q1B, Q1C, Q1D, and Q1E guidances. 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

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 part 314 for submission of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information for the submission of biological license applications under 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information for OTC monograph drug products have been approved under OMB control number 0910–0340. The collections of information for the submission and review of biosimilar product applications and related biosimilar user fee requirements have been approved under OMB control number 0910–0718. The collections of information for the submission and review of correspondence for generic drug products and related generic drug user fee requirements have been approved under OMB control number 0910–0727. The collections of information for current good manufacturing practice in the manufacture, processing, packing and storage of finished pharmaceuticals in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 201 for labeling of prescription drug and biological products have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft 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: June 18, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11552 Filed 6–23–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Guidance on Referrals for Potential Criminal Enforcement

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: This notice describes the Department of Health and Human Services' (HHS or the Department) plans to address regulations that impose criminal liability under the recent Executive Order (E.O.) on *Fighting Overcriminalization in Federal Regulations.*

FOR FURTHER INFORMATION CONTACT: Bob Foster, Deputy General Counsel, (202) 260–3324, *robert.foster@hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 9, 2025, President Donald J. Trump issued E.O. 14294, *Fighting Overcriminalization in Federal Regulations;* 90 FR 20363 (published May 14, 2025). Section 7 of E.O. 14294 provides that within 45 days of the E.O., and in consultation with the Attorney General, each agency should publish guidance in the **Federal Register** describing its plan to address regulations that impose criminal liability.

Consistent with that requirement, HHS advises the public that by May 9, 2026, the Department, in consultation with the Attorney General, will provide to the Director of the Office of Management and Budget a report containing: (1) a list of all criminal regulatory offenses [1] enforceable by the Department or the Department of Justice (DOJ); and (2) for each such criminal regulatory offense, the range of potential criminal penalties for a violation and the applicable mens rea [2] for the criminal regulatory offense.

This notice also announces a general policy, subject to appropriate exceptions and to the extent consistent with law, that when HHS is deciding whether to refer alleged violations of criminal regulatory offenses to DOJ, officers and employees of HHS should consider, among other factors:

- the harm or risk of harm, pecuniary or otherwise, caused by the alleged offense;
- the potential gain to the putative defendant that could result from the offense;
- whether the putative defendant held specialized knowledge, expertise, or was licensed in an industry related to the rule or regulation at issue; and
- evidence, if any is available, of the putative defendant's general awareness of the unlawfulness of his conduct as well as his knowledge or lack thereof of the regulation at issue.

This general policy is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies,

[1] ''Criminal regulatory offense'' means a Federal regulation that is enforceable by a criminal penalty. E.O. 14294, sec. 3(b).

[2] ''Mens rea'' means the state of mind that by law must be proven to convict a particular defendant of a particular crime. E.O. 14294, sec. 3(c).