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 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jennifer Gao, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2135, Silver Spring, MD 20993–0002, 240–402–4683; 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

FDA is announcing the availability of a guidance for industry entitled ''Cancer Clinical Trial Eligibility Criteria: Available Therapy in Non-Curative Settings.'' The guidance provides recommendations regarding the inclusion of patients who have not received available therapy for their cancer in clinical trials of investigational cancer drugs and biological products in the non-curative setting. For the purposes of this guidance, non-curative is generally defined as: (1) unresectable, locally advanced, or metastatic disease in solid tumors or (2) hematologic malignancies with unfavorable long-term overall survival.

Under 21 CFR part 312, which applies to clinical investigations of drugs and biological products, FDA must determine that study subjects are not exposed to an unreasonable and significant risk of illness or injury (312.42(b)(1)(i) and (b)(2)(i)) to allow such trials to proceed. Therefore, in clinical trials evaluating investigational cancer drugs, eligibility criteria should generally require that patients have received available therapy(ies) that offer the potential for cure in a substantial proportion of patients. Alternatively, such available therapy should be administered to all patients in the trial, where the investigational drug is added to such therapy. However, eligibility criteria in which patients receive an investigational drug(s) in lieu of available therapy are reasonable in the non-curative setting when patients have been provided with adequate information to make an informed decision on trial participation. The guidance describes information that should be included in the informed consent and includes recommendations regarding evaluation of results when this approach is taken.

This guidance finalizes the draft guidance entitled ''Cancer Clinical Trial Eligibility Criteria: Available Therapy in Non-Curative Settings'' issued on June 24, 2021 (86 FR 33710). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include additional recommendations for safety evaluation in early stage dose escalation studies.

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 ''Cancer Clinical Trial Eligibility Criteria: Available Therapy in Non-Curative Settings.'' 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. 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 part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

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

Dated: July 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16074 Filed 7–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4417]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Pharmaceutical Voluntary Consensus Standard Recognition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by August 26, 2022.

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/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Pharmaceutical Voluntary Consensus Standard Recognition.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Pharmaceutical Voluntary Consensus Standard Recognition

OMB Control Number 0910—NEW

This information collection helps support implementation of FDA's Center for Drug Evaluation and Research's (CDER) Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality. The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) and Circular A–119 by the Office of Management and Budget (OMB) have established Federal Government policies to improve the internal management of the executive branch by directing agencies to use voluntary consensus standards developed or adopted by a standards developing organization—rather than Government-unique standards—except where these standards are inconsistent with applicable law or otherwise impractical. We have developed Agency guidance to communicate procedures respondents can follow to submit requests for recognition of a voluntary consensus standard, as well as procedures CDER will follow when a request is received. The draft guidance entitled, ''CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality'' (February 2019), outlines justifications for why a standard may be recognized wholly, partly, or not at all. (The draft guidance is available on our website at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cders-program-recognition-voluntary-consensus-standards-related-pharmaceutical-quality.*) [1] The guidance also communicates that interested parties may request recognition of a standard, allowing CDER to:

- receive a candidate consensus standard, with relevant information (*e.g.,* the scope of the standard and the purpose), from internal or external parties for informal recognition;
- determine whether to informally recognize a standard in whole or in part following an internal scientific evaluation; and
- list the informally recognized standards in a publicly searchable database on FDA's website, accompanied by an information sheet describing the scope and the extent of informal recognition of that standard and other relevant information.

In the **Federal Register** of February 14, 2019 (84 FR 4076), FDA published a 60-day notice announcing the availability of the draft guidance and invited comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Guidance activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total burden hours	Hourly wage rate	Total respondent costs
Submission of request for recognition of a voluntary consensus standard (page 2, page 5, section B.1)	9	1	9	1	9	$87.12	$784.08

Based on our experience with similar programs, we assume nine respondents will each submit one request for standard recognition annually, and that it will require 1 hour to prepare. We also assume industry wage rates of $87.12, for a total cost of $784.08 annually.

Dated: July 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16063 Filed 7–26–22; 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 08N146B, 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 compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for

[1] When final, this guidance will represent FDA's current thinking on this topic.