TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total
New domestic facility registration; 1.230–1.233	9,795	1	9,795	2.7	26,447
New foreign facility registration; 1.230–1.233	13,697	1	13,697	8.7	119,164
Updates; 1.234	53,836	1	53,836	1.2	64,603
Cancellations; 1.235	6,390	1	6,390	1	6,390
Biennial renewals; 1.235	97,883	1	97,883	0.38	37,196
3rd party registration verification	41,256	1	41,256	0.25	10,314
U.S. Agent verification	57,070	1	57,070	0.25	14,268
Total			279,927		278,382

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16062 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–2020–D–1802]

Cancer Clinical Trial Eligibility Criteria: Available Therapy in Non-Curative Settings; 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 ''Cancer Clinical Trial Eligibility Criteria: Available Therapy in Non-Curative Settings.'' The guidance provides recommendations to sponsors of clinical trials of investigational cancer drugs regarding the inclusion of patients who have not previously received available therapy (commonly referred to as existing treatment options) for their cancer in the non-curative setting. This guidance finalizes the draft guidance of the same title issued on June 24, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on July 27, 2022.

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–2020–D–1802 for ''Cancer Clinical Trial Eligibility Criteria: Available Therapy in Non-Curative Settings.'' 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 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.