reasonable assurance of safety and effectiveness for these devices. The proposed special controls would require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional premarket notification (510(k)) submission for a device within the scope of the proposed order.

Currently, manufacturers of HIV serological diagnostic and supplemental tests and HIV NAT diagnostic and supplemental tests are subject to FDA regulations in part 820 (21 CFR part 820), which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. Manufacturers are required to maintain complaint files and to review and evaluate complaints for these devices under § 820.198 (21 CFR 820.198).

Complaints required to be reported in the annual logs under the proposed special controls, such as certain complaints involving unusually high invalid rates or issues with users conducting the test, may not meet the definition of a medical device report required to be reported to FDA under 21 CFR part 803 (medical device reporting; currently approved under OMB control number 0910–0437), but could potentially affect the safety and efficacy of these devices. If the proposed order is finalized, we intend to review the information in the complaint logs in a timely manner and engage with manufacturers as necessary. The submission of the complaint log would provide us with earlier notification of concerns and enable us to determine whether they have been adequately addressed. The Agency usually would not evaluate this kind of complaint information until an FDA inspection, which typically occurs less frequently than annually. We believe implementing these specific reporting measures as part of the special controls would be necessary to provide a reasonable assurance of safety and effectiveness for HIV diagnostic and supplemental tests subject to the proposed order.

Description of Respondents: The respondents to the information collection are manufacturers of HIV diagnostic and supplemental test devices that would be subject to the proposed order, if finalized.

Finalizing the proposed order would add classification regulations for these devices in 21 CFR part 866 (Immunology and Microbiology Devices) at 21 CFR 866.3956 for the HIV serological diagnostic and supplemental tests, and 21 CFR 866.3957 for the HIV NAT diagnostic and supplemental tests, and establish special controls necessary to provide reasonable assurance of their safety and effectiveness. As described above, the special controls would require the submission of a log of all complaints annually for a period of 5 years following FDA clearance of a traditional 510(k) submission for one of these devices.

We estimate the reporting burden hours associated with the proposed order, if finalized, to be approximately 30 reporting burden hours.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR citation, activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Proposed 21 CFR 866.3956(b)(1)(iii) and 866.3957(b)(1)(iii), Submission of log to FDA	10	1	10	3	30

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

We base our estimate of the average burden per response on our experience with other types of annual report submissions. We base our estimate of the number of affected respondents on the expected number of manufacturers that would be submitting a 510(k) for a new device or changes to an existing device that would require a 510(k).

As noted above, manufacturers of the devices subject to the proposed order must already maintain complaint files and review and evaluate complaints under § 820.198. If the proposed order is finalized as proposed, we estimate it would take a manufacturer approximately 3 hours annually to review their existing records, prepare the complaint log, and submit it to FDA. Although respondents may submit the information electronically through the FDA Electronic Submission Gateway, on paper, or electronic media (*e.g.,* CD, DVD) to the Center for Biologics Evaluation and Research's Document Control Center, we assume that all manufacturers will submit their logs electronically.

Dated: June 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13580 Filed 6–24–21; 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: Approach to Available Therapy in Non-Curative Settings; Draft Guidance for Sponsors; 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 sponsors entitled ''Cancer Clinical Trial Eligibility Criteria: Approach to Available Therapy in Non-Curative Settings.'' The draft 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. The draft guidance is intended to facilitate increased clinical trial options for patients with non-curable cancers by recognizing that, with appropriate informed consent, it may be reasonable for patients to be eligible for inclusion in trials of investigational cancer drugs, regardless of whether they have received available therapy, in the non-curative setting.

DATES: Submit either electronic or written comments on the draft guidance by August 24, 2021 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–2020–D–1802 for ''Cancer Clinical Trial Eligibility Criteria: Approach to 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 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 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 draft 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; Chana Weinstock, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2357, Silver Spring, MD 20993–0002, 240–402–2625; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for sponsors entitled ''Cancer Clinical Trial Eligibility Criteria: Approach to Available Therapy in Non-Curative Settings.'' The draft 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 purpose of this draft guidance, non-curative is defined as circumstances where there is extremely low likelihood for cure or for prolonged and/or near normal survival with available therapies (*i.e.,* hematologic malignancies or solid tumors that are unresectable, locally advanced, or metastatic cancer with unfavorable long-term overall survival).

For clinical trials of products regulated under part 312 (21 CFR part 312), FDA must determine that study subjects are not exposed to an unreasonable and significant risk of illness or injury (21 CFR 312.42(b)(1)(i) and (b)(2)(i)) to allow such trials to proceed. Therefore, eligibility criteria should generally require that patients have received available therapy(ies) that offer the potential for cure in a substantial proportion of patients in clinical trials evaluating investigational cancer drugs. 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 draft guidance also describes information that should be included in the informed consent when this approach is taken. The draft guidance further includes recommendations regarding efficacy analyses when this approach is taken.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA

on ''Cancer Clinical Trial Eligibility Criteria: Approach to 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 draft 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: June 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13585 Filed 6–24–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0352]

Intent To Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products for Over-the-Counter Use; Reopening of Comment Period

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

ACTION: Notice of intent; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is reopening the comment period for public scoping on the environmental impact statement (EIS) described in the notice entitled ''Intent To Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products for Over-the-Counter Use'' that appeared in the **Federal Register** of May 13, 2021. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for public scoping on the EIS identified in the notice published May 13, 2021 (86 FR 26224). To ensure the Agency considers your comments before it begins work on the draft EIS, submit either electronic or written comments on the scoping process discussed in the notice by July 14, 2021. If a virtual public scoping meeting is scheduled, FDA will announce the date and time via the weblink ''Environmental Impact Statement (EIS) for Certain Sunscreen Drug Products'' on the Agency's web page ''Guidance, Compliance, & Regulatory Information,'' available at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information.*

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 14, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 14, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2021–N–0352 for ''Intent To Prepare an Environmental Impact Statement for Certain Sunscreen Drug Products for Over-the-Counter Use.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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