to notify the Secretary in accordance with section 506J.'' Thus, manufacturers of a device on the 506J Device List must notify FDA in accordance with 506J of the FD&C Act for each such device. For more information, manufacturers should see the 506J Device List web page, available at *https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/506j-device-list.* Additionally, consistent with section 506J(h) of the FD&C Act, FDA is proposing to clarify for stakeholders that manufacturers may submit, and FDA may receive, voluntary notifications regarding supply chain issues at any time, unrelated to the declaration or potential declaration of a PHE.

The guidance documents include additional voluntary items that manufacturers could provide the Agency, including additional information about device manufacturing and supply, and updates to initial notifications.

Respondents may notify FDA about an interruption or permanent discontinuance in device manufacturing (506J notification) on our website at *https://fda-cdrh.my.salesforce-sites.com/shortages/.*

In the **Federal Register** of November 28, 2023 (88 FR 83134), FDA published a 60-day notice requesting public 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 [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Shortages outreach data collection	1,000	4	4,000	1	4,000
Information collection under section 506J	8,400	1	8,400	0.25 (15 minutes)	2,100
Additional voluntary collections related to section 506J	8,400	1	8,400	0.25 (15 minutes)	2,100
Total			20,800		8,200

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

I. Shortages Outreach Data Collection

FDA bases these estimates on our recent experience and informal direct contact with respondents. We estimate up to 1,000 manufacturers, distributors, healthcare systems, healthcare providers, group purchasing organizations, and sterilizers for which there may be targeted outreach because their devices may be essential to the response effort. This targeted outreach will be conducted periodically either to obtain primary data or to verify/validate updated data (although additional outreach may be undertaken as needed). The data being requested represent common data elements that respondents monitor and track as part of routine business operations and, therefore, are readily available. It is anticipated that for most respondents, the estimated time to fulfill CDRH's data request will not exceed 1 hour per request, or 4 hours per year.

II. Information Collection Under Section 506J of the FD&C Act and Related Voluntary Collections

Based on current registration and listing data (approved under OMB control number 0910–0625), we estimate the number of respondents that will submit a notification under section 506J of the FD&C Act to be approximately 20 percent of currently registered manufacturers. Data from our Registration and Listing system indicate that there are approximately 42,000 unique FDA Establishment Identification registered manufacturers. Therefore, we estimate 8,400 respondents per year. We believe that the burden, including the provision of required information under section 506J of the FD&C Act, as well as additional voluntary information (including additional issues that may impact the availability of the device, such as information about critical suppliers, potential mitigations, production capacity and market share, and notification updates), is minimal and such information is readily available to respondents. Therefore, we estimate the burden of this information collection to be 15 minutes or less per notification.

Since the last OMB approval, we have updated the Number of Respondents and Average Burden per Response for the Shortages Outreach Data Collection element based on our recent experience with the information collection and informal direct contact with respondents. The updates result in an adjustment of an additional 3,000 hours and 2,000 responses annually.

Dated: April 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09023 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3743]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Electronic Records: Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that a collection of information entitled ''Electronic Records: Electronic Signatures'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 22, 2024, the Agency submitted a proposed collection of information entitled ''Electronic Records: Electronic Signatures'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

number. OMB has now approved the information collection and has assigned OMB control number 0910–0303. The approval expires on March 31, 2027. A copy of the supporting statement for this information collection is available on the internet at *https://www.reginfo.gov/public/do/PRAMain.*

Dated: April 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08953 Filed 4–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1376]

Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications; Draft Guidance for Industry, Institutional Review Boards, and Clinical Investigators; 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, institutional review boards (IRBs), and clinical investigators entitled ''Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.'' This draft guidance is one in a series of guidances that provide recommendations regarding eligibility criteria for clinical trials of investigational drugs regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation Research (CBER) for the treatment of cancer. Specifically, this draft guidance includes recommendations regarding the appropriate use of washout periods and concomitant medication exclusions.

DATES: Submit either electronic or written comments on the draft guidance by June 25, 2024 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–2024–D–1376 for ''Cancer Clinical Trial Eligibility Criteria: Washout Periods and Concomitant Medications.'' 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: Jamie Brewer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2319, Silver Spring, MD 20993, 240–402–4463; or Vishal Bhatnagar, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2113, Silver Spring, MD 20993, 240–402–3696; or James Myers, 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.