compliance determination if applicable. The certificate issuance fees will be set by CMS at levels sufficient to recover the full costs of administering the operational provisions of CLIA, including approval and monitoring of proficiency testing programs and accrediting bodies and implementing Federal requirements. Fees will also be collected by CMS to cover the costs of inspecting non-accredited laboratories and validating accrediting laboratories based on the lab's volume and scope of testing. Currently, CMS contracts with 50 State agencies to conduct surveys of all participating health care facilities. As part of their contract, CMS reimburses the State agencies for the reasonable cost of conducting surveys. This information collection gathers the information necessary to reimburse State agencies for a reasonable cost. *Form Number:* CMS–102 and CMS–105 (OMB control number: 0938–0599); *Frequency:* Yearly/Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 34. (For policy questions regarding this collection contact Eric Powell at 312–886–0791).

Dated: November 22, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–26201 Filed 11–27–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4597]

Agency Information Collection Activities; Proposed Collection; Comment Request; Shortages Data Collections

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collections associated with Shortages Data Collections and with notifications to FDA of an interruption or permanent discontinuance in manufacturing of certain medical devices as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Either electronic or written comments on the collection of information must be submitted by January 29, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 29, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2023–N–4597 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Shortages Data Collections.'' 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 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.

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: Under the PRA (44 U.S.C. 3501–3521), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Shortages Data Collections

OMB Control Number 0910–0491—Extension

Under section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)), the Commissioner of Food and Drugs is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA. After the events of September 11, 2001, and as part of broader counterterrorism and emergency preparedness activities, FDA's Center for Devices and Radiological Health (CDRH) began developing operational plans and interventions that would enable CDRH to anticipate and respond to medical device shortages that might arise in the context of federally declared disasters/emergencies or regulatory actions. In particular, CDRH identified the need to acquire and maintain detailed data on domestic inventory, manufacturing capabilities, distribution plans, and raw material constraints for medical devices that would be in high demand and/or would be vulnerable to shortages in specific disaster/emergency situations or following specific regulatory actions. Such data could support prospective risk assessment, help inform risk mitigation strategies, support real-time decision making by the Department of Health and Human Services (HHS) during actual emergencies or emergency preparedness exercises, and mitigate or prevent harm to the public health.

This voluntary data collection process consists of outreach to firms that have been identified as producing or distributing medical devices that may be considered essential to the response effort. In this initial outreach, the intent and goals of the data collection effort will be described, and the specific data request made. Data are collected, using the least burdensome methods, in a structured manner to answer specific questions. After the initial outreach, we will request updates to the information periodically to keep the data current and accurate. Additional followup correspondence may occasionally be needed to verify/validate data, confirm receipt of followup correspondence(s), and/or request additional details to further inform FDA's public health response.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136) was enacted on March 27, 2020. Section 3121 of the CARES Act amended the FD&C Act by adding section 506J to the FD&C Act (21 U.S.C. 356j). Section 506J of the FD&C Act provides FDA with new authorities intended to help prevent or mitigate medical device shortages by requiring medical device manufacturers to inform FDA about changes in device manufacturing that could potentially lead to a device shortage. Apprised with that information, section 506J of the FD&C Act authorizes FDA to take several actions that may help to mitigate or avoid supply disruptions.

Section 506J of the FD&C Act requires manufacturers of certain devices,[1] to notify FDA ''of a permanent discontinuance in the manufacture of the device'' or ''an interruption of the manufacture of the device that is likely to lead to a meaningful disruption in supply of that device in the United States'' during or in advance of a declared public health emergency, and the reason for such discontinuance or interruption.[2] Section 506J of the FD&C Act requires FDA to take action based on that information, including (1) publicly posting a list of devices it determines to be in shortage, (2) publicly posting the reasons for the shortage, and (3) issuing letters to manufacturers that fail to comply with the notification requirements of section 506J of the FD&C Act.

On December 29, 2022, the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act was signed into law as part of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) (hereafter referred to as the ''FY 2023 Omnibus''). Section 2514(c) of the fiscal year (FY) 2023 Omnibus directed FDA to issue or revise guidance regarding requirements under section 506J of the FD&C Act and include a list of each device product code for which a manufacturer of such device is required to notify FDA in accordance with section 506J. Section 2514 of the FY 2023 Omnibus amended section 506J of the FD&C Act to add section 506J(h), ''Additional Notifications'' and directed FDA to issue guidance ''to facilitate voluntary notifications.''

In the **Federal Register** of November 17, 2023 (88 FR 80310), FDA announced the availability of the final guidance entitled ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' [3] and the draft guidance entitled ''Select Updates for the 506J Guidance: 506J Device List and Additional Notifications.'' [4] The final guidance, ''Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act'' (hereafter referred to as the ''506J Guidance'') assists stakeholders in the Agency's implementation of section 506J. This guidance serves as the baseline for information about notifications under section 506J during or in advance of any public health emergency (PHE). FDA provides additional clarification on who is

[1] Under section 506J of the FD&C Act, manufacturers of the following devices must notify FDA of an interruption or permanent discontinuance in manufacturing:

- Devices that are critical to public health during a public health emergency, including those that are life-supporting, life-sustaining, or intended for use in emergency medical care or during surgery; or
- Devices for which FDA determines information on potential meaningful supply disruptions is needed during a public health emergency. See section 506J(a)(1), (2) of the FD&C Act.

[2] See section 506J(a) of the FD&C Act.

[3] *https://www.fda.gov/media/155245/download.*

[4] *https://www.fda.gov/media/173800/download.*

required to notify FDA, when such notifications are required, what information FDA expects manufacturers to include in such notifications, and how to submit notifications. Additionally, FDA describes how FDA determines that a device is in shortage and additional actions FDA may take to help prevent or mitigate a potential device shortage.

In the draft guidance ''Select Updates for the 506J Guidance: 506J Device List and Additional Notifications,'' FDA proposes updates to the 506J Guidance. Specifically, FDA has developed a list of devices, by FDA product code, for which a manufacturer of such devices is required to notify FDA in accordance with section 506J (hereafter referred to as the ''506J Device List''). The 506J Device List is based on the requirements under section 506J(a) of the FD&C Act. In section 2514 of the FY 2023 Omnibus, Congress directed FDA to issue guidance on the requirements under section 506J and to include ''a list of each device product code for which a manufacturer of such device is required 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 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), 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/.*

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: November 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–26199 Filed 11–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–2101]

Determination of Regulatory Review Period for Purposes of Patent Extension; Korsuva

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Korsuva and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.