CMS–R–144 is required from States quarterly to report utilization for any drugs paid for during that quarter. Effective July 1, 2021, the MDRP is updating to a new Medicaid Drug Programs (MDP) system which will now accept a delimited text file format, Comma Separated Values (.CSV), in addition to the current Text (.TXT) file format. We have also increased several file format data field sizes in order to accommodate the higher priced drugs that are entering the market. These changes in conjunction with numerous edits to verbiage are applicable to Form CMS–R–144. Separately, we are also updating corresponding collection of information requests (OMB 0938–0578 and OMB 0938–0676) so that all the MDP file formats, field sizes, and verbiage will align across the MDRP. Form CMS–368 has been revised by removing the DUR State Contact information and description ''Drug Utilization Review (DUR) Program.'' This information is now accounted for under OMB 0938–0659. *Form Number:* CMS–368 and –R–144 (OMB control number: 0938–0582); *Frequency:* Quarterly and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 290; *Total Annual Hours:* 13,669. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

Dated: February 17, 2021.

William N. Parham, III,

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

[FR Doc. 2021–03535 Filed 2–22–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0197]

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 or Agency) 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 revision 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: Submit either electronic or written comments on the collection of information by April 26, 2021.

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 April 26, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 26, 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–2012–N–0197 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Shortages Data Collection.'' 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 revision 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—Revision

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 who 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 will be collected, using least burdensome methods, in a structured manner to answer specific questions. After the initial outreach, we will request updates to the information on a quarterly basis 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. These data, collected under section 1003(d)(2) of the FD&C Act, are currently approved under OMB control number 0910–0491. We have made minor changes to this ''Shortages data collection'' at this time (see first row of table 1 of this document) to reflect additional learnings from recent experience.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted on March 27, 2020. Section 3121 of the CARES Act amended the FD&C Act by adding section 506J (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 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 in ''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 (PHE), and the reason for such discontinuance or interruption.[2] Section 506J 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.

Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive PRA requirements with respect to voluntary collections of information during a PHE, as declared by the Secretary, or when a disease or disorder is significantly likely to become a PHE. In 2020 FDA published the immediately in effect guidance document entitled ''Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID–19 Public Health Emergency (Revised)—Guidance for Industry and Food and Drug Administration Staff'' (see 86 FR 106, January 4, 2021) [3] to implement section 506J of the FD&C Act, as it relates to device shortages and potential device shortages occurring during the COVID–19 pandemic, for the duration of the COVID–19 PHE. The guidance includes

[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) and (2) of the FD&C Act.

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

[3] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-cdrh-permanent-discontinuance-or-interruption-manufacturing-device-under-section-506j-fdc.*

additional voluntary items that manufacturers could provide the Agency, including additional information about device manufacturing and supply, and updates to initial notifications. While PRA requirements for the voluntary information collections recommended in the guidance are waived [4] during the COVID–19 pandemic PHE using this new authority, mandatory collections such as those under section 506J of the FD&C Act may not be part of the waiver. FDA requested emergency clearance under 44 U.S.C. 3507(j) and 5 CFR 1320.13 to immediately approve revision of OMB control number 0910–0491 to add the information collection required by section 506J of the FD&C Act, as amended. The emergency clearance approval expires on May 31, 2021; therefore, CDRH is requesting a revision of OMB control number 0910–0491 to add the information collection required by 506J of the FD&C Act.

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

I. Shortages Data Collection Currently Approved Under OMB Control Number 0910–0491

FDA bases these estimates on past experiences with direct contact with the medical device manufacturers and distributors, and anticipated changes in the medical device manufacturing and distributions patterns for the specific devices that may be monitored. FDA estimates that there may be up to 500 manufacturers and distributors for which there may be targeted outreach because their devices may be essential to the response effort. This targeted outreach will be conducted quarterly to either obtain primary data or to verify/validate updated data (although additional outreach may be undertaken as needed).

From the manufacturer and distributor's point of view, the data being requested represent common data elements that they monitor and track as part of routine business operations and therefore are readily available. It is anticipated that for most manufacturers and distributors, the estimated time to fulfill CDRH's data request will not exceed 30 minutes per request, or 2 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 & Listing system indicates 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 as well as the provision of required information under section 506J of the FD&C Act—as well as additional voluntary information related to the determination (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 manufacturers of the applicable devices. Therefore, we estimate the burden of this information collection to be 15 minutes or less per determination and notification.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Shortages data collection	500	4	2,000	0.5 (30 minutes)	1,000
Information collection under section 506J of the FD&C Act.	8,400	1	8,400	0.25 (15 minutes)	2,100
Additional voluntary collections related to section 506J of the FD&C Act.	8,400	1	8,400	0.25 (15 minutes)	2,100
Total			18,800		5,200

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

The information collection reflects a revision to add the information collection required by section 506J of the FD&C Act (as amended by section 3121 of the CARES Act) and additional voluntary collections related to section 506J of the FD&C Act to OMB control number 0910–0491.

Upon review of OMB control number 0910–0491, we note that there is a data-entry error in the RISC/ORIA Combined Information System (ROCIS) for a previous information collection approval on February 3, 2020. Currently, ROCIS lists the total burden hours for that approval as 390 hours; the correct total burden hour estimate is 520 hours. This error has carried through to the current total hour burden listed in ROCIS as 2,481 hours for the approval on November 24, 2020; the correct total burden hour estimate should be 2,611 hours. We will correct this error upon submission of this information collection request to OMB.

Additionally, we have updated the number of respondents in each information collection to reflect our current data and estimations.

These revisions and adjustments reflect an overall increase of 2,589 hours to the (corrected) estimated total burden.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03630 Filed 2–22–21; 8:45 am]

BILLING CODE 4164–01–P

[4] See *https://aspe.hhs.gov/system/files/pdf/258866/FDA-PHE-PRA-Waiver-Notice_COVID-19_03.19.20.pdf.*