

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

CMS-10437 Generic Social Marketing & Consumer Testing Research

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently

approved collection; *Title of Information Collection:* Generic Social Marketing & Consumer Testing Research; *Use:* The purpose of this submission is to extend the approval of the generic clearance for a program of consumer research aimed at a broad audience of those affected by CMS programs including Medicare, Medicaid, Children’s Health Insurance Program (CHIP), and health insurance exchanges. This program extends strategic efforts to reach and tailor communications to beneficiaries, caregivers, providers, stakeholders, and any other audiences that would support the Agency in improving the functioning of the health care system, improve patient care and outcomes, and reduce costs without sacrificing quality of care. The information collected will be used to create a streamlined and proactive process for collection of data and utilizing the feedback on service delivery for continuous improvement of communication activities aimed at diverse CMS audiences. The generic clearance will allow rapid response to inform CMS initiatives using a mixture of qualitative and quantitative consumer research strategies (including formative research studies and methodological tests) to improve communication with key CMS audiences. As new information resources and persuasive technologies are developed, they can be tested and evaluated for beneficiary response to the materials and delivery channels. Results will inform communication development and information architecture as well as allow for continuous quality improvement. The overall goal is to maximize the extent to which consumers have access to useful sources of CMS program information in a form that can help them make the most of their benefits and options. The activities under this clearance involve social marketing and consumer research using samples of self-selected customers, as well as convenience samples, and quota samples, with respondents selected either to cover a broad range of customers or to include specific characteristics related to certain products or services. All collection of information under this clearance will utilize a subset of items drawn from a core collection of customizable items referred to as the Social Marketing and Consumer Testing Item Bank. This item bank is designed to establish a set of pre-approved generic question that can be drawn upon to allow for the rapid turn-around consumer testing required for us to communicate more effectively with our audiences. The questions in

the item bank are divided into two major categories. One set focuses on characteristics of individuals and is intended primarily for participant screening and for use in structured quantitative on-line or telephone surveys. The other set is less structured and is designed for use in qualitative one-on-one and small group discussions or collecting information related to subjective impressions of test materials. Results will be compiled and disseminated so that future communication can be informed by the testing results. We will use the findings to create the greatest possible public benefit. Form Number: CMS-10437 (OMB control number: 0938-1247); Frequency: Yearly; Affected Public: Individuals; Number of Respondents: 7,732; Number of Responses: 61,992; Total Annual Hours: 26,688. (For policy questions regarding this collection contact Hemaligiri Gosai at 410-786-0000.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-09041 Filed 4-25-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-4597]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Shortages Data Collections

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 (including recommendations) on the collection of information by May 28, 2024.

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 OMB control number for this information collection is 0910–0491. Also include the FDA docket number found in brackets in the heading of this document.

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, PRASStaff@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.

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 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

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.

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 of the FD&C Act. This final guidance serves as the baseline for information about notifications under section 506J of the FD&C Act during or in advance of any public health emergency (PHE). FDA provides additional clarification on who is 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 of the FD&C Act (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 of the FD&C Act and to include “a list of each device product code for which a manufacturer of such device is required

³ <https://www.fda.gov/media/155245/download>.

⁴ <https://www.fda.gov/media/173800/download>.

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]

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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