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 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 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240–402–8926; 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 guidance for industry entitled ''Bispecific Antibody Development Programs.'' The regulatory pathway for evaluation of monoclonal antibodies is well established, but additional guidance is warranted regarding antibody-based products that target more than one antigen. This guidance addresses challenges that may arise during development of bispecific antibodies and provides recommendations regarding the type of data necessary to support approval.

This guidance finalizes the draft guidance of the same title issued on April 19, 2019 (84 FR 16512). FDA considered comments received on the draft guidance as the guidance was finalized. In addition to minor editorial changes to improve clarity, changes from the draft to the final guidance include:

- Emphasis on discussing unique aspects of the quality, nonclinical, and clinical development programs for bispecific antibodies
- Clarification regarding potential immunogenicity associated with bispecific antibodies
- Clarification of clinical assessments comparing a bispecific antibody and an approved monospecific product(s)

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Bispecific Antibody Development Programs.'' 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 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *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,* or *https://www.regulations.gov.*

Dated: May 18, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11026 Filed 5–24–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0197]

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, Agency, or we) 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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by June 24, 2021.

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, *PRAStaff@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—Revision

Under section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act (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 follow-up correspondence may occasionally be needed to verify/validate data, confirm receipt of follow-up 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 to the FD&C Act (21 U.S.C. 356j). Section 506J 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 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.

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 (42 U.S.C. 247d). This new subsection gives the HHS Secretary (Secretary) the authority to waive PRA requirements with respect to voluntary collections of information during a public health emergency, as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency. In 2020, FDA published the guidance 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)'' (86 FR 106),[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 public health emergency. The guidance includes 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, public health emergency 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.

In the **Federal Register** of February 23, 2021 (86 FR 10972), 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:

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 periodically 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.

[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] See *https://www.fda.gov/media/137712/download.*

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

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, 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: May 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11028 Filed 5–24–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Infectious Etiology of AD.

Date: June 24–25, 2021.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Joshua Jin-Hyouk Park, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–6208, *joshua.park4@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 20, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–11046 Filed 5–24–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Aging Special Emphasis Panel, June 14, 2021, 11:30 a.m. to June 14, 2021, 03:30 p.m., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD, 20892 which was published in the **Federal Register** on April 06, 2021, 86 FR 17847.

The meeting notice is amended to change the date of the meeting from June 14, 2021 to July 6, 2021. The meeting is closed to the public.

Dated: May 20, 2021.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–11030 Filed 5–24–21; 8:45 am]

BILLING CODE 4140–01–P