

determined necessary and appropriate by the Secretaries.

- Ali Khawar—Secretary of Labor's Designee.
 - Carol Weiser—Secretary of the Treasury's Designee.
 - Rogelyn McLean—Secretary of Health and Human Services' Designee.
 - Gamunu Wijetunge—Department of Transportation—National Highway Traffic Safety Administration.
 - Suzanne Prentiss—State Insurance Regulators.
 - Adam Beck—Health Insurance Providers.
 - Patricia Kelmar—Consumer Advocacy Groups.
 - Gary Wingrove—Patient Advocacy Groups.
 - Ayobami Ogunsola—State and Local Governments.
 - Ritu Sahni—Physician specializing in emergency, trauma, cardiac, or stroke.
 - Peter Lawrence—State Emergency Medical Services Officials.
 - Shawn Baird—Emergency Medical Technicians, Paramedics, and Other Emergency Medical Services Personnel.
 - Edward Van Horne—Representative of Various Segments of the Ground Ambulance Industry.
 - Regina Godette-Crawford—Representative of Various Segments of the Ground Ambulance Industry.
 - Rhonda Holden—Representative of Various Segments of the Ground Ambulance Industry.
 - Loren Adler—Additional Representative determined necessary and appropriate by the Secretaries
- The GAPB Advisory Committee Roster is also available on the GAPB Advisory Committee website at: <https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb>. All future updates to the Advisory Committee Roster will be published on this website.

III. Meeting Agenda

The second public meeting of the GAPB Advisory Committee will take place on August 16, 2023. During this meeting, the Committee will review and discuss preliminary findings and recommendations from its two subcommittees. The agenda will cover the following topics:

- Preliminary findings and recommendations of the GAPB Advisory Committee's subcommittee on Network Adequacy and Cost/Payment Structures.
- Preliminary findings and recommendations of the GAPB Advisory Committee's subcommittee on Public/Consumer Disclosures and Protections.

A more detailed agenda and materials will be made available prior to the

meeting on the GAPB Advisory Committee website (listed previously).

Anticipated Dates for Future GAPB Advisory Committee Meetings

The Centers for Medicare & Medicaid Services (CMS) expects to convene future GAPB Advisory Committee Meetings on the following dates: October 31, 2023 and November 1, 2023. Agendas and registration information for future meeting dates will be published in the **Federal Register** and on the GAPB Advisory Committee website closer to the anticipated meeting dates, which are subject to change.

IV. Public Participation

The August 16, 2023, GAPB Advisory Committee meeting will be open to the public. Attendance may be limited due to virtual meeting constraints. Interested parties are encouraged to register as far in advance of the meeting as possible. To register for the meeting visit: <https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb>. CMS is committed to providing equal access to this meeting for all participants and to ensuring section 508 compliance. Closed captioning will be provided. To request alternative formats or services because of a disability, such as sign language interpreters or other ancillary aids, refer to the appropriate contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

V. Submitting Written Comments

Members of the public may submit written comments for consideration by the Committee at any time via email to gapbadvisorycommittee@cms.hhs.gov. Additionally, members of the public will have the opportunity to submit comments during the August 16, 2023, virtual meeting through the chat feature of the Zoom webinar platform. Members of the public are encouraged to submit lengthy written comments on topics discussed during the meeting to the email address in the **DATES** section by September 5, 2023, to ensure timely consideration by the Committee.

VI. Viewing Documents

You may view the documents discussed in this notice at <https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb>.

The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the

Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Evell J. Barco Holland,
Federal Register Liaison, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2459]

Agency Information Collection Activities; Proposed Collection; Comment Request; Product Jurisdiction and Combination Products

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 collection associated with product jurisdiction and combination product regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by September 29, 2023.

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 September 29, 2023. 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-2459 for "Product Jurisdiction and Combination Products." 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRStaff@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 extension of the existing 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.

Product Jurisdiction and Combination Products—21 CFR Parts 3 and 4

OMB Control Number 0910-0523—Extension

This information collection helps support implementation of statutory requirements that govern product jurisdiction and combination products. Congress expressly directed FDA to assign combination products to the appropriate Agency component for regulation as set forth in section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353(g)). Congress also expressly directed FDA to determine the classification of a product as a drug, biological product, device, or combination product, or the component of the Agency that will regulate the product, as applicable, in response to a request submitted under section 563 of the FD&C Act (21 U.S.C. 360bbb-2).

Regulations in 21 CFR part 3 provide for product classification determinations and FDA designation on which Agency component will have primary jurisdiction for any drug, device, biological, or combination product, where such jurisdiction is unclear or in dispute. These determinations are made by our Office of Combination Products (OCP) upon receiving Requests for Designation (RFDs). We maintain a web page that includes contact and resource information pertaining to the RFDs process at <https://www.fda.gov/combination-products/jurisdictional-information>. As communicated on our web page, FDA welcomes comments from interested stakeholders on issues pertaining to OCP and encourages medical product developers to contact us if they are uncertain about the classification or assignment of their products and with questions regarding premarket or postmarket considerations for combination products. A dedicated mailbox is established at combination@fda.gov.

Similar to the RFD process, we have established the Pre-RFD process for sponsors to obtain preliminary, nonbinding feedback regarding medical product classification and assignment. Although Forms FDA 5003, 5004, and 5005 (pre-request and request for designation forms) were previously developed to facilitate information collection for Pre-RFDs and RFDs, we have more recently issued the following Agency guidance documents to provide instruction and recommendations to respondents regarding the submission of RFDs and Pre-RFDs.

- The guidance document entitled, "How to Write a Request for Designation" (April 2011), provides instruction regarding the information that needs to be submitted to OCP in an RFD as described in 21 CFR 3.7. The guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd>.

- The guidance document entitled "How to Prepare a Pre-Request for Designation," (February 2018) was developed to assist sponsors in obtaining a preliminary, non-binding assessment regarding the classification

and assignment of products from OCP through the Pre-RFD process. The guidance explains the Pre-RFD process and helps a sponsor understand the type of information to provide in a Pre-RFD submission. The guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-prepare-pre-request-designation-pre-rfd>.

- This information collection also includes burden associated with Combination Product Agreement Meetings (CPAM) requests. The guidance document entitled, "Requesting FDA Feedback on Combination Products," (December 2020) was developed to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions and to describe best practices for FDA and sponsors when interacting on these topics. The guidance is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products>.

The guidance documents were issued consistent with our good guidance practice regulations in 21 CFR 10.115,

which provide for public comment at any time.

The information collection also includes regulations in 21 CFR part 4 that govern current good manufacturing practice requirements and postmarketing safety requirements for combination products. We expect, however, that burden attendant to the associated recordkeeping, reporting, and/or disclosure activities is already accounted for in approved information collections that apply to drug, device, and/or biologic products specifically and respectively. Therefore, we do not ascribe separate burden in this information collection request for the activities generated by these requirements.

Respondents to the information collection are sponsors of medical products, including combination products. Based on submissions received by OCP during fiscal years 2020, 2021, and 2022, we account for 135 respondents annually.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3.7; request for designation (RFD)	55	1	55	24	1,320
Pre-RFD submissions	77	1	77	24	1,848
CPAM requests	3	1	3	25	75
Total					3,243

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

Our estimated burden reflects a decrease in the number of respondents (four respondents) and a corresponding decrease in total hours (96 hours). Based on a recent evaluation of CPAM requests received from each product center in fiscal years 2020, 2021, and 2022, our estimated annual burden for CPAM requests remains unchanged.

Dated: July 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2707]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Petitions for Exemption From Preemption

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 the information collection provisions of our reporting requirements contained in FDA regulations governing state petitions for exemption from preemption.

DATES: Either electronic or written comments on the collection of information must be submitted by September 29, 2023.

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 September 29, 2023. Comments received by mail/hand delivery/courier (for