

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with regulatory provisions, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board). This meeting is open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person listed in the addresses section below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcome to listen to the meeting by joining the audio conference (information below). The audio conference line has 150 ports for callers.

DATES: The meeting will be held on March 9, 2023, from 11 a.m. to 1 p.m., EDT. Written comments must be received on or before March 2, 2023.

ADDRESSES: You may submit comments by mail to: Dr. Rashaun Roberts, National Institute for Occupational Safety and Health (NIOSH), CDC, 1090 Tusculum Avenue, Mailstop C-24, Cincinnati, Ohio 45226.

Meeting Information: Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1-866-659-0537; the pass code is 9933701.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, NIOSH, CDC, 1090 Tusculum Avenue, Mailstop C-24, Cincinnati, Ohio 45226; Telephone: (513) 533-6800; Email: ocas@cdc.gov.

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the

Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC.

The Advisory Board's charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 13889 on March 22, 2022, and will terminate on March 22, 2024.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Considered: The agenda will include discussions on the following: Work Group and Subcommittee Reports; Update on the Status of SEC Petitions; and Plans for the April 2023 Advisory Board Meeting. Agenda items are subject to change as priorities dictate.

For additional information, please contact 1-800-232-4636 (toll free).

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

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Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1800-NC]

Inflation Reduction Act (IRA) Initial Program Guidance; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' initial guidance for the Medicare Part B and Part D Prescription Drug Inflation Rebate Program for the implementation of the Inflation Reduction Act. CMS will be releasing additional Inflation Reduction Act-related guidance; all can be viewed on the dedicated Inflation Reduction Act section of the CMS website at <https://www.cms.gov/inflation-reduction-act-and-medicare/>.

DATES: Comments must be received by March 11, 2023.

ADDRESSES: Written comments should be sent to IRAREbateandNegotiation@cms.hhs.gov with the relevant subject line, either "Medicare Part B Inflation Rebate Comments" or "Medicare Part D Inflation Rebate Comments."

SUPPLEMENTARY INFORMATION: The Inflation Reduction Act was signed into law on August 16, 2022. Section 11101 of the Inflation Reduction Act added a new section 1847A(i) to the Social Security Act (herein referred to as "the Act,"), which establishes a requirement for manufacturers to pay Medicare Part B rebates for single source drugs and biological products with prices that increase faster than the rate of inflation for a calendar quarter to the Federal Supplementary Medical Insurance Trust Fund, and provides for lower Part B beneficiary cost sharing on these drugs and biologicals.

Section 11102 of the Inflation Reduction Act added a new section 1860D-14B to the Act, which establishes a requirement for manufacturers to pay rebates to the

Federal Supplementary Medical Insurance Trust Fund for certain Part D drugs when prices increase faster than the rate of inflation for each 12-month applicable period. Collectively, this program to implement these rebates is referred to as the Medicare Prescription Drug Inflation Rebate Program, or the Inflation Rebate Program.

CMS will be releasing additional Inflation Reduction Act-related guidance; all can be viewed on the dedicated Inflation Reduction Act section of the CMS website at <https://www.cms.gov/inflation-reduction-act-and-medicare/>.

To obtain copies of initial guidance and other Inflation Reduction Act-related documents, please access the CMS Inflation Reduction Act website by copying and pasting the following web address into your web browser: <https://www.cms.gov/inflation-reduction-act-and-medicare>. If interested in receiving CMS Inflation Reduction Act updates by email, individuals may sign up for CMS Inflation Reduction Act's email updates at <https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/EmailUpdates>.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: February 8, 2023.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023-02974 Filed 2-9-23; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0366]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the 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 associated with certain FDA advisory committee activities.

DATES: Either electronic or written comments on the collection of information must be submitted by April 14, 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 April 14, 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-2017-N-0366 for "FDA Advisory Committees." 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