

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Advisory Board on Radiation and Worker Health (ABRWH), Subcommittee for Procedures Reviews (SPR), National Institute for Occupational Safety and Health (NIOSH)

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

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Subcommittee for Procedures Reviews (SPR) 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 below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcomed 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 September 29, 2022, from 11:00 a.m. to 3:30 p.m., EDT. Written comments must be received on or before September 22, 2022.

**ADDRESSES:** You may submit comments by mail to: Sherri Diana, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C-34, 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, Toll Free 1(800) CDC-INFO, Email: [ocas@cdc.gov](mailto: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 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:* The 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, advise 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. SPR is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor (Oak Ridge Associated Universities—ORAU).

*Matters To Be Considered:* The agenda will include discussions on the following: a) Discussions of technical guidance documents related to: Texas City Chemicals, Weldon Spring Plant, Birdsboro Steel and Foundry Company, Grand Junction Facilities, Peek Street Facility, dose reconstruction default assumptions and methods, and template dose reconstruction methodologies (b) Preparation for December 2022 Full ABRWH meeting, and (c) Newly Issued Guidance Documents and Supplemental topics. Agenda items are subject to change as priorities dictate. For

additional information, please contact Toll Free 1(800) 232-4636.

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

### Food and Drug Administration

[Docket No. FDA-2022-N-1728]

#### AbbVie Inc., et al.; Withdrawal of Approval of 30 New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 30 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of September 15, 2022.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, [Kimberly.Lehrfeld@fda.hhs.gov](mailto:Kimberly.Lehrfeld@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.