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.*

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.

Kalwant Smagh,

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

[FR Doc. 2022–17617 Filed 8–15–22; 8:45 am]

BILLING CODE 4163–18–P

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.*

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.

Application No.	Drug	Applicant
NDA 005856	Tridione (trimethadione) Tablets, 150 milligrams (mg); Tridione (trimethadione) Capsules, 300 mg; Tridione (trimethadione) Oral Solution, 200 mg/5 milliliters (mL).	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 010679	Cantil (mepenzolate bromide) Tablets, 25 mg; Cantil (mepenzolate bromide) Solution, 25 mg/5 mL.	Sanofi-Aventis U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 016042	Dyazide (hydrochlorothiazide/triamterene) Capsules, 25 mg/37.5 mg and 25 mg/50 mg.	GlaxoSmithKline LLC, 5 Crescent Dr., Philadelphia, PA 19112.
NDA 017531	Tigan (trimethobenzamide hydrochloride (HCl)) Capsules, 300 mg	King Pharmaceuticals LLC, 235 East 42nd St., New York, NY 10017.
NDA 017565	Norinyl 1+ 35 (ethinyl estradiol and norethindrone) Tablets, 0.035 mg/1 mg.	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940.
NDA 017766	NephrAmine 5.4% (amino acids) Injection, 5.4% (5.4 grams (g)/100 mL).	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109.
NDA 018053	Bupivacaine HCl Injection, 0.25%, 0.5%, and 0.75%	Hospira, Inc., 275 North Field Dr., Bldg. H1–3S, Lake Forest, IL 60045.
NDA 019558	Prinivil (lisinopril) Tablets, 2.5 mg, 5 mg, 10 mg, 20 mg, and 40 mg	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., 1 Merck Dr., Whitehouse Station, NJ 08889–0100.
NDA 019805	Heparin Sodium in 5% Dextrose Injection, 4,000 Units/100 mL and 5,000 Units/100 mL.	Hospira, Inc.
NDA 019813	Duragesic (fentanyl transdermal system) Extended-release Film, 12.5 micrograms (mcg)/hour, 25 mcg/hour, 37.5 mcg/hour, 50 mcg/hour, 75 mcg/hour, and 100 mcg/hour.	Janssen Research & Development, LLC, 1000 U.S. Route 202, Raritan, NJ 08869.
NDA 019917	Morphine Sulfate Injection, 0.5 mg/mL	ICU Medical, Inc., 600 N. Field Dr., Lake Forest, IL 60045.
NDA 020156	Videx (didanosine) Powder for Oral Solution, 10 mg/mL	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 020570	Quadramet (samarium sm 153 lexidronam pentasodium) Injection, 50 millicuries/mL.	Lantheus Medical Imaging, Inc., 331 Treble Cove Rd., Bldg. 300–2, North Billerica, MA 01862.
NDA 020591	Tarka (trandolapril and verapamil HCl) Extended-release Tablets, 1 mg/240 mg, 2 mg/180 mg, 2 mg/240 mg, and 4 mg/240 mg.	AbbVie Inc.
NDA 020658	Requip (ropinirole HCl) Tablets, equivalent to (EQ) 0.25 mg base, EQ 0.5 mg base, EQ 1 mg base, EQ 2 mg base, EQ 3 mg base, EQ 4 mg base, and EQ 5 mg base.	GlaxoSmithKline LLC.
NDA 020685	Crixivan (indinavir sulfate) Capsules, EQ 100 mg base, EQ 200 mg base, EQ 333 mg base, and EQ 400 mg base.	Merck Sharp & Dohme Corp.
NDA 020732	Subutex (buprenorphine HCl), sublingual tablets, EQ 2mg base and EQ 8mg base.	Indivior Inc., 10710 Midlothian Turnpike, Suite 125, North Chesterfield, VA 23235.
NDA 020733	Suboxone (buprenorphine HCl and naloxone HCl) Sublingual Tablets, EQ 2 mg base/EQ 0.5 mg base, and EQ 8 mg base/EQ 2 mg base.	Do.
NDA 020946	Preven Emergency Contraceptive Kit (ethinyl estradiol and levonorgestrel) Tablets, 0.05 mg/0.25 mg.	Teva Branded Pharmaceutical Products R&D, Inc., 145 Brandywine Pkwy., West Chester, PA 19380.
NDA 021183	Videx EC (didanosine) Delayed-release Capsules, 125 mg, 200 mg, 250 mg, and 400 mg.	Bristol-Myers Squibb Co.
NDA 021627	Namenda (memantine HCl) Oral Solution, 2 mg/mL	Allergan Sales, LLC.
NDA 022008	Requip XL (ropinirole HCl) Extended-release Tablets, EQ 2 mg base, EQ 3 mg base, EQ 4 mg base, EQ 6 mg base, EQ 8 mg base, and EQ 12 mg base.	GlaxoSmithKline LLC.
NDA 022205	Giazo (balsalazide disodium) Tablets, 1.1 g	Salix Pharmaceuticals, Inc., 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 022246	Metozolv ODT (metoclopramide HCl) Orally Disintegrating Tablets, EQ 5 mg base and EQ 10 mg base.	Do.
NDA 022401	Twynsta (amlodipine besylate and telmisartan) Tablets, EQ 5 mg base/40 mg, EQ 5 mg base/80 mg, EQ 10 mg base/40 mg, and EQ 10 mg base/80 mg.	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877.
NDA 050662	Biaxin Filmtab (clarithromycin,) Tablets, 250 mg and 500 mg	AbbVie Inc.
NDA 050698	Biaxin Granules for Oral Suspension (clarithromycin) 125 mg/5 mL, 187 mg/5 mL, and 250 mg/5 mL.	Do.
NDA 050775	Biaxin XL Filmtab (clarithromycin) Extended-release Tablets, 500 mg ...	Do.
NDA 209305	Eskata (hydrogen peroxide) Topical Solution, 40%	Aclaris Therapeutics, Inc., 640 Lee Rd., Suite 200, Wayne, PA 19087.
NDA 211210	Qmiiz ODT (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg.	TerSera Therapeutics LLC, 520 Lake Cook Rd., Suite 500, Deerfield, IL 60015.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of September 15, 2022. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on September 15, 2022 may continue to be dispensed until the

inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: August 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17534 Filed 8–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0275–30D]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before September 15, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041. When submitting comments or requesting information, please include the document identifier OS–0990–0275–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of Collection: Performance Data System (PDS).

Type of Collection: Extension.

OMB No.: 0990–0275.

Abstract: This request for clearance is to extend data collection activities for a currently approved collection using the OMB approved Performance Data System (PDS) (OMB No. 0990–0275), the tool used by the Office of Minority Health (OMH) to collect program management and performance data for all OMH-funded projects. The revised data collection instrument keeps all the same data elements, but includes additional formatting to clarify data elements. Additionally, a few columns were reordered in order to make the form more intuitive. Grantee data collection via the UDS (original data collection system) was first approved by OMB on June 7, 2004 (OMB No. 0990–275).

Need and Proposed Use of the Information: The clearance is needed to continue data collection using the PDS, a system that enables OMH to comply with Federal reporting requirements and monitor and evaluate performance by enabling the efficient collection of performance-oriented data tied to OMH-wide performance reporting needs. The ability to monitor and evaluate performance in this manner, and to work towards continuous program improvement are basic functions that OMH must be able to accomplish to carry out its mandate with the most effective and appropriate use of resources.

Likely Respondents: Respondents for this data collection include the project directors for OMH-funded projects and/or the date entry persons for each OMH-funded project. Affected public includes non-profit institutions, State, Local, or Tribal Governments.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

	Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Burden	OMH Grantee	PDS	100	4	20/60	133.33
		Record Keeping	100	4	25/60	166.67
Total			100	4	45/60	300

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2022–17564 Filed 8–15–22; 8:45 am]

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