Application No.	Drug	Applicant
ANDA 074400	Diflunisal Tablets, 250 mg and 500 mg	Do.
ANDA 074432	Diclofenac Sodium Delayed Release Tablets, 50 mg and 75 mg.	Pliva, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 074460	Piroxicam Capsules, 10 mg and 20 mg	Watson Laboratories, Inc.
ANDA 074585	Indapamide Tablets, 1.25 mg and 2.5 mg	Do.
ANDA 074698	Baclofen Tablets, 10 mg and 20 mg	Do.
ANDA 074711	Mexiletine HCl Capsules, 150 mg, 200 mg and 250 mg	Do.
ANDA 074723	Diclofenac Sodium Delayed Release Tablets, 50 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074852	Diltiazem HCl Extended Release Capsules, 120 mg, 180 mg, and 240 mg.	Actavis Laboratories FL, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 074865	Mexiletine HCl Capsules, 150 mg, 200 mg, and 250 mg	Watson Laboratories, Inc.
ANDA 074870	Acyclovir Tablets, 400 mg and 800 mg	Actavis Elizabeth LLC (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 075101	Acyclovir Capsules, 200 mg	Watson Laboratories, Inc.
ANDA 076022	Fluoxetine HCl Capsules, EQ 10 mg base and EQ 20 mg base.	Carlsbad Technology, Inc., 5922 Farnsworth Ct., Carlsbad, CA 92008.
ANDA 078345	Prednisolone Sodium Phosphate Solution, EQ 15 mg base/5 milliliters (mL).	Amneal Pharmaceuticals, 85 Adams Ave., Hauppauge, NY 11788.
ANDA 080521	Isoniazid Tablets, 300 mg	Watson Laboratories, Inc.
ANDA 086537	Nitroglycerin Controlled-Release Capsules, 6.5 mg	Lumara Health, Inc., 1100 Winter St., Suite 3000, Waltham, MA 02451.
ANDA 086889	Disulfiram Tablets, 250 mg	Watson Laboratories, Inc.
ANDA 086890	Disulfiram Tablets, 500 mg	Watson Laboratories, Inc.
ANDA 087975	Nitroglycerin Controlled-Release Capsules, 2.5 mg	Sandoz Inc., 100 College Rd. West, Princeton, NJ 08540.
ANDA 087976	Nitroglycerin Controlled-Release Capsules, 6.5 mg	Do.
ANDA 088509	Nitroglycerin Controlled-Release Capsules, 9 mg	Do.
ANDA 090833	Carbidopa/Levodopa and Entacapone Tablets, 18.75 mg/200 mg/75 mg, 25 mg/200 mg/100 mg, 31.25 mg/200 mg/125 mg, 37.5 mg/200 mg/150 mg, and 50 mg/200 mg/200 mg.	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC., 6451 Main St., Morton Grove, IL 60053.
ANDA 200771	Irinotecan HCl Injection, 40 mg/2 mL (20 mg/mL) and 100 mg/5 mL (20 mg/mL).	Heritage Pharmaceuticals Inc. d/b/a/Avet Pharmaceuticals Inc. U.S. Agent for Emcure Pharmaceuticals Limited, One Tower Center Blvd., East Brunswick, NJ 08816.
ANDA 202063	Gemcitabine HCl for Injection, EQ 200 mg base/vial; EQ 1 gram base/vial.	Do.
ANDA 204437	Sodium Fluoride 18 Injection, 10–200 millicurie (mCi)/mL	UCSF Radiopharmaceutical Facility, 185 Berry St., Suite 350, San Francisco, CA 94107.
ANDA 208444	Choline C–11 Injection, 4–33.1 mCi/mL	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of July 26, 2021. Approval of each entire application is withdrawn, including any strengths and dosage forms 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 July 26, 2021 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: June 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13593 Filed 6–24–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

Name of Committee: Interagency Autism Coordinating Committee.

Date: July 21–22, 2021.

Time: Wednesday, July 21, 2021—1:00 p.m. to 4:00 p.m. ET, *https://videocast.nih.gov/watch=42326;* Thursday, July 22, 2021—2:00 p.m. to 5:00 p.m. ET, *https://videocast.nih.gov/watch=42327.*

Agenda: To discuss business, updates, and issues related to ASD research and services activities.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (*www.iacc.hhs.gov*) prior to the meeting. Pre-registration is recommended.

Deadlines: Written/Virtual Public Comment Due Date: Friday, July 2, 2021, by

5:00 p.m. ET. For instructions, see below. Public Comments provided via Live Feedback Form during the meeting: No preregistration required. For instructions, see *https://iacc.hhs.gov/meetings/iacc-meetings/live-feedback.shtml.*

Contact Person: Ms. Rebecca Martin, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Bethesda, MD 20892–9669, Phone: 301–435–9269, Email: *IACCPublicInquiries@mail.nih.gov.*

Public Comments: The IACC welcomes public comments from members of the autism community. Comments may be submitted in writing via email to *IACCPublicInquiries@mail.nih.gov* or using the web form at: *https://iacc.hhs.gov/meetings/public-comments/submit/index.jsp* by 5:00 p.m. ET on Friday, July 2, 2021. Comments may be addressed to the Interagency Autism Coordinating Committee. A limited number of slots are available for individuals to provide a 2–3-minute summary or excerpt of their comment to the committee live during the virtual meeting using the virtual platform. For those interested in that opportunity, please indicate ''Interested in providing virtual comment'' in your written submission, along with your name, address, email, phone number, and professional/organizational affiliation so that OARC staff can contact you if a slot is available for you to provide a summary or excerpt of your comment via the virtual platform during the meeting. For any given meeting, priority for virtual comment slots will be given to commenters who have not previously provided virtual comments in the current calendar year. This will help ensure that as many individuals as possible have an opportunity to share comments. Commenters going over their allotted 3-minute slot may be asked to conclude immediately to allow other comments and the rest of the meeting to proceed on schedule.

Public comments received by 5:00 p.m. ET on Friday, July 2, 2021, will be provided to the Committee prior to the meeting for their consideration. Any written comments received after 5:00 p.m. ET, Friday, July 2, 2021, may be provided to the Committee either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. All public comments become part of the public record. Attachments of copyrighted publications are not permitted, but web links or citations for any copyrighted works cited may be provided. For public comment guidelines, see: *https://iacc.hhs.gov/meetings/public-comments/guidelines/.*

Individuals may also submit public comments to the IACC via a Live Feedback Form accessible from the webcast page on the days of the meeting during the time period announced. No pre-registration for Live Feedback comments is required. The link to the form will be accessible on the NIH Videocast website at *https://videocast.nih.gov* and instructions are available on the IACC website: *https://iacc.hhs.gov/meetings/iacc-meetings/live-feedback.shtml.* This format is best suited for brief questions and comments for the committee. Submissions will be provided to the IACC and will become a part of the public record.

Technical Issues: If you experience any technical problems with the webcast or conference call, please send an email to *IACCPublicInquiries@mail.nih.gov* or use the Live Feedback form on the NIH Videocast meeting page.

Meeting schedule subject to change.

Disability Accommodations: All IACC Full Meetings provide Closed Captioning through the NIH videocast website. Individuals whose full participation in the meeting will require special accommodations (*e.g.,* sign language or interpreting services, etc.) must submit a request to the Contact Person listed on the notice at least seven (7) business days prior to the meeting. Such requests should include a detailed description of the accommodation needed and a way for the IACC to contact the requester if more information is needed to fill the request. Special requests should be made at least seven (7) business days prior to the meeting; last minute requests may be made but may not be possible to accommodate.

More Information: Information about the IACC is available on the website: *http://www.iacc.hhs.gov.*

Dated: June 21, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–13528 Filed 6–24–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

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

The meetings 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 Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Outstanding Investigator Award (OIA)—R35.

Date: August 4–5, 2021.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209–B, Bethesda, MD 20892, (301) 827–7953, *kristen.page@nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Catalyze Enabling Technologies.

Date: August 18, 2021.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Kristin Goltry, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209–B, Bethesda, MD 20892, (301) 435–0297, *goltrykl@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Catalyze Product Definition.

Date: August 19, 2021.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Kristin Goltry, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209–B, Bethesda, MD 20892, (301) 435–0297, *goltrykl@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Early Stage Investigatory (EIA) R35 Review Meeting.

Date: August 25, 2021.

Time: 10:00 a.m. to 6:00 p.m.