teleconferencing and/or video conferencing platform.

The Committee will receive updates on the accelerated approval program in oncology and two new drug applications (NDAs) approved under 21 CFR 314.500 (subpart H, accelerated approval regulations) that have not met their agreed-upon milestones for completion of confirmatory trial(s). Confirmatory trials are postmarketing studies to verify and describe the clinical benefit of a drug after it receives accelerated approval. These updates will provide information on the status of all accelerated approvals granted in oncology, including products with delayed confirmatory trials, and the status of confirmatory trials for the specific NDAs to be discussed, including any ongoing and planned trials.

The two products to be discussed are: (1) FOLOTYN (pralatrexate), NDA 022468 submitted by Acrotech Biopharma Inc, indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL), and (2) BELEODAQ (belinostat), NDA 206256 submitted by Acrotech Biopharma Inc, indicated for the treatment of patients with relapsed or refractory PTCL. Based on the updates provided, the Committee will have a general discussion about delayed confirmatory trials as well as a focused discussion on next steps for the two products, FOLOTYN (pralatrexate) and BELEODAQ (belinostat), approved for PTCL. The overall goal will be the continued optimization of the accelerated approval process with a focus on decreasing the amount of time to verify (or fail to verify) clinical benefit, while continuing to provide early availability of promising oncology products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

The meeting will include slide presentations with audio and video components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. All electronic and written submissions to the Docket (see **ADDRESSES**) on or before November 1, 2023, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. eastern time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 24, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 25, 2023.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: September 29, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–21984 Filed 10–3–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–N–3859]**

### Dr. Reddy's Laboratories, Inc.; Withdrawal of Approval of 11 Abbreviated New Drug Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is withdrawing approval of 11 abbreviated new drug applications (ANDAs) from Dr. Reddy's Laboratories, Inc. The applicant 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 November 3, 2023.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** The applicant listed in the table has informed FDA that these drug products are no longer marketed and has requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicant has also, by their request, waived the 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 |
|---|---|---|
| ANDA 090177 ..... | Oxycodone and Acetaminophen Tablets, 3.25 milligrams (mg); 2.5 mg, 325 mg; 5 mg, 325 mg; 7.5 mg, 325 mg; 10 mg, 500 mg; 7.5 mg, 650 mg; 10 mg. | Dr. Reddy's Laboratories, Inc., U.S. Agent for Dr. Reddy's Laboratories SA, 107 College Rd. East, Princeton NJ 08540. |
| ANDA 091313 ..... | Oxycodone Hydrochloride (HCl) Tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg. | Do. |
| ANDA 091670 ..... | Oxycodone and Aspirin Tablets, 325 mg; 4.8355 mg ..... | Do. |
| ANDA 203107 ..... | Oxycodone HCl Capsules, 5 mg ..... | Do. |
| ANDA 203335 ..... | Butalbital, Aspirin, Caffeine, and Codeine Phosphate Capsules, 325 mg; 50 mg; 40 mg; 30 mg. | Do. |
| ANDA 203807 ..... | Clozapine Tablets, 25 mg, 50 mg, 100 mg, 200 mg ..... | Do. |
| ANDA 204092 ..... | Oxycodone HCl Oral Solution 100 mg/5 milliliters ..... | Do. |
| ANDA 205386 ..... | Morphine Sulfate Extended-Release Tablets, 15 mg, 30 mg, 60 mg, 100 mg. | Do. |
| ANDA 206329 ..... | Fentanyl Citrate Tablets, Equivalent to (EQ) 0.1 mg base, EQ 0.2 mg base, EQ 0.3 mg base, EQ 0.4 mg base, EQ 0.6 mg base, EQ 0.8 mg base. | Do. |
| ANDA 206953 ..... | Buprenorphine HCl and Naloxone HCl Tablets, EQ 2 mg base, EQ 0.5 mg base; EQ 8 mg base, EQ 2 mg base. | Do. |
| ANDA 207270 ..... | Morphine Sulfate Tablets, 15 mg, 30 mg ..... | Do. |

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 3, 2023. 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 November 3, 2023 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: September 29, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–21992 Filed 10–3–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Announcement of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders Meeting and Solicitation for Written Comments

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of Intergovernmental and External Affairs, White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders.

**ACTION:** Notice of meeting and solicitation for written comments.

**SUMMARY:** The U.S. Department of Health and Human Services (HHS) announces the next meeting of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders (Commission) and the solicitation of written comments regarding the advancement of equity, justice, and opportunity for Asian American, Native Hawaiian, and Pacific Islander (AA and NHPI) communities. The meeting is open to the public and will be held in Washington, DC on October 25 and October 26, 2023. Virtual attendance will be available through livestream. The Commission is working to accomplish its mission to provide independent advice and recommendations to the President on ways to advance equity, justice, and opportunity for AA and NHPI communities.

**DATES:** The Commission will meet on October 25, 2023, from 9:00 a.m. Eastern Time (ET) to 4:30 p.m. ET and October 26, 2023, from 9:00 a.m. ET to 2:00 p.m. ET. The final location and agenda will be posted on the website for the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders: *https://www.hhs.gov/about/whiaanhpi/commission/index.html* when this information becomes available.

**ADDRESSES:** Members of the public may attend virtually. Registration is required through the following link: *https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpis-tickets-715434733547?aff=oddtdtcreator.*

**FOR FURTHER INFORMATION CONTACT:** Viviane Chao, Designated Federal Officer, President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders, U.S. Department of Health and Human Services, Office of the Secretary, Office of Intergovernmental and External Affairs, Hubert H. Humphrey Building, Room 620E, 200 Independence Ave. SW, Washington, DC 20201; email: *AANHPICommission@hhs.gov;* telephone: (202) 690–6060.

**SUPPLEMENTARY INFORMATION:** The meeting is the seventh in a series of Federal advisory committee meetings regarding the development of recommendations to advance equity, justice, and opportunity for AA and NHPI communities. The meeting is open to the public and will be live streamed. The Commission, co-chaired by HHS Secretary Xavier Becerra and the U.S. Trade Representative Ambassador Katherine Tai, advises the President on: the development, monitoring, and coordination of executive branch efforts to advance equity, justice, and opportunity for AA and NHPI communities in the United States, including efforts to close gaps in health, socioeconomic, employment, and educational outcomes; policies to address and end anti-Asian bias, xenophobia, racism, and nativism, and opportunities for the executive branch to advance inclusion, belonging, and public awareness of the diversity and accomplishments of AA and NHPI people, cultures, and histories; policies, programs, and initiatives to prevent, report, respond to, and track anti-Asian hate crimes and hate incidents; ways in which the Federal Government can build on the capacity and contributions of AA and NHPI communities through equitable Federal funding, grantmaking, and employment opportunities; policies and practices to improve research and equitable data disaggregation regarding AA and NHPI communities; policies and practices to improve language