

[www.healthaffairs.org/doi/full/10.1377/hlthaff.25.2.313](http://www.healthaffairs.org/doi/full/10.1377/hlthaff.25.2.313).

Dated: September 16, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–21433 Filed 9–18–24; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2024–N–4289]

**Allergan, Inc., et al.; Withdrawal of Approval of Nine Abbreviated New Drug Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of nine abbreviated new drug applications (ANDAs) 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of October 21, 2024.

**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, 301–796–3471, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The applicants listed in table 1 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.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 062452 ....	Gentamicin Sulfate solution/drop, Equivalent to (EQ) 0.3% base.	Allergan, Inc., 2525 Dupont Dr., P.O. Box 19534, Irvine, CA 92612.
ANDA 064124 ....	Cefuroxime Sodium injectable, EQ 7.5 grams (g) base/vial ...	ACS Dobfar S.p.A., U.S. Agent Interchem Corp., 120 Route 17 North, Paramus, NJ 07652.
ANDA 077151 ....	Milrinone Lactate injectable, EQ 40 milligrams (mg) base/200 milliliters (mL) (EQ 0.2 mg base/mL) EQ 20 mg base/100 mL (EQ 0.2 mg base/mL).	Woodward Pharma Services, LLC, 47220 Cartier Dr., Suite A, Wixom, MI 48393.
ANDA 079032 ....	Ondansetron Hydrochloride preservative free injectable, EQ 2 mg base/mL.	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967.
ANDA 079075 ....	Fentanyl Citrate tablet, EQ 0.1 mg base, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base.	Watson Laboratories, Inc., (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A, Parsippany, NJ 07054.
ANDA 206155 ....	Olanzapine tablet, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg.	Indoco Remedies Ltd., U.S. Agent RegCon Solutions, LLC, 9920 Pacific Heights Blvd., Suite 250, San Diego, CA 92121.
ANDA 206204 ....	Piperacillin Sodium and Tazobactam Sodium injectable, EQ 12 gm base/vial, EQ 1.5 gm base/vial.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 207919 ....	Acyclovir Sodium injectable, EQ 50 mg base/mL .....	Dr. Reddy's Laboratories, Inc., 107 College Rd. East, Princeton, NJ 08540.
ANDA 209708 ....	Mivacurium Chloride solution, EQ 10 mg base/5 mL (EQ 2 mg base/mL) and EQ 20 mg base/10 mL (EQ 2 mg base/mL).	Woodward Pharma Services, LLC.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of October 21, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on October 21, 2024 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 16, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–21432 Filed 9–18–24; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2024–N–4189]

**Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments: Strain Selection for Influenza Vaccines**

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related

Biological Products Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The Committee will meet in open session to discuss three separate topics. At least one portion of the meeting will be closed to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held virtually on October 10, 2024, from 8 a.m. to 5:30 p.m. Eastern Time.

**ADDRESSES:** All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform.

The online web conference meeting will be available at the following link on the day of the meeting: <https://youtube.com/live/RXdJ2BfutAE>.

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2024-N-4189. The docket will close on October 9, 2024. 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 October 9, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before October 2, 2024, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

#### *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-2024-N-4189 for "Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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." FDA 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 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 the 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:**

Kathleen Hayes or Sussan Paydar, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993-0002, 202-657-8533, [CBERVRBPAC@fda.hhs.gov](mailto:CBERVRBPAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

#### **SUPPLEMENTARY INFORMATION:**

*Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On October 10, 2024, the Committee will meet in open session to discuss the following three separate topics. Under Topic I, the Committee will discuss and make recommendations on the strain selection for the influenza virus vaccines for the 2025 southern hemisphere influenza season. Under Topic II, the Committee will discuss pandemic preparedness for highly pathogenic avian influenza virus

including considerations for vaccine composition for (H5) vaccines. Under Topic III, the Committee will hear an overview of the research programs in the Laboratory of Pediatric & Respiratory Viral Diseases and the Laboratory of DNA Viruses in the Division of Viral Products, Office of Vaccines Research and Review, CBER. After the open session, the meeting will be closed to the public for committee deliberations.

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:** On October 10, 2024, from 8 a.m. to 11:15 a.m. Eastern Time for Topic I, from 11:45 a.m. to 2:30 p.m. Eastern Time for Topic II, and from 2:40 p.m. to 4:20 p.m. Eastern Time for Topic III, the meeting is open to the public. 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 October 2, 2024, will be provided to the Committee. Comments received on or after October 2, 2024, and by October 9, 2024, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 9:55 a.m. to 10:15 a.m. Eastern Time for Topic I, 1:10 p.m. to 1:30 p.m. Eastern Time for Topic II, and 4 p.m. to 4:20 p.m. Eastern Time for Topic III. 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, along with their names, email addresses, and direct contact phone numbers of proposed participants, and an indication of the approximate time requested to make their presentation on or before 12 p.m. Eastern Time on September 24, 2024. 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 September 27, 2024.

**Closed Committee Deliberations:** On October 10, 2024, the meeting will be closed from 4:30 p.m. to 5:30 p.m. to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the individual investigators' research programs, along with other information, will be discussed during this session. We believe that public discussion of these discussions and committee recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto: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 Kathleen Hayes or Sussan Paydar (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. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: September 16, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-0022]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form 3601a

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by October 21, 2024.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0511. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Medical Device User Fee Cover Sheet, Form FDA 3601 and Device Facility User Fee Cover Sheet, Form FDA 3601a

*OMB Control Number 0910-0511—Revision*

This information collection supports the FDA medical device and device user fee programs. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee and Modernization Act of 2002