

with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy.

On April 29, 2021, the committee will receive updates on the following products: (1) BLA 125514/S-024, trade name KEYTRUDA (pembrolizumab), submitted by Merck Sharpe & Dohme Corp., indicated for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 [Combined Positive Score (CPS)  $\geq 1$ ] as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy; (2) BLA 125514/S-042, trade name KEYTRUDA (pembrolizumab), submitted by Merck Sharpe & Dohme Corp., indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib; and (3) BLA 125554/S-041, trade name OPDIVO (nivolumab), submitted by Bristol-Myers Squibb Company, indicated as a single agent for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

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 meeting room 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 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 submitted to the Docket (see **ADDRESSES**) on or before April 20, 2021, will be provided to the committee. Oral presentations from the public will be scheduled from approximately 2:55 p.m. to 3:15 p.m. Eastern Time on April 27, 2021. Oral presentations from the public will also be scheduled between approximately 10:55 a.m. to 11:15 a.m., and 2:10 p.m.

to 2:30 p.m. Eastern Time on April 28, 2021. Oral presentations from the public will also be scheduled between approximately 10:50 a.m. to 11:10 a.m., 1:55 p.m. to 2:15 p.m., and from 4:40 p.m. to 5 p.m. Eastern Time on April 29, 2021. 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 April 12, 2021. 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 April 13, 2021.

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 Joyce Yu and Takyiah Stevenson (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. app. 2).

Dated: March 8, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-2143]

### Withdrawal of Approval of Five Abbreviated New Drug Applications for Bacitracin for Injection

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is withdrawing approval of five abbreviated new drug applications (ANDAs) from multiple holders. Akorn Inc. (Akorn), Mylan ASI LLC (Mylan), Pfizer Inc. (Pfizer), X-GEN Pharmaceuticals, Inc. (X-GEN), and Fresenius Kabi USA, LLC (Fresenius) have requested withdrawal of approval of their respective applications and have waived their opportunity for a hearing.

**DATES:** Approval is withdrawn as of March 12, 2021.

**FOR FURTHER INFORMATION CONTACT:** Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3600, [Sungjoon.Chi@fda.hhs.gov](mailto:Sungjoon.Chi@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On January 31, 2020, FDA requested that all application holders of bacitracin for injection voluntarily request withdrawal of approval of their applications under § 314.150(d) (21 CFR 314.150(d)). Bacitracin for injection is an antibiotic for intramuscular administration, the use of which is limited to the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug. Bacitracin for injection poses serious risks, including nephrotoxicity and anaphylactic reactions. Healthcare professionals generally no longer use bacitracin for injection to treat infants with pneumonia and empyema because other effective FDA-approved treatments are available that do not have these risks.

In April 2019, FDA's Antimicrobial Drugs Advisory Committee met and discussed the safety and effectiveness of bacitracin for injection. The advisory committee voted almost unanimously, with one abstention, that the benefits of bacitracin for intramuscular injection do not outweigh its risks, including nephrotoxicity and anaphylactic reactions, for the drug's only approved indication. Based on FDA's review of

currently available data and information, the Agency believes that the potential problems associated with bacitracin for injection are sufficiently serious that the drug should be removed from the market.

In separate letters dated February 5, 2020, Akorn and Mylan requested that FDA withdraw approval of ANDAs 206719 and 090211 under § 314.150(d). Akorn and Mylan each waived their opportunity for a hearing. Additionally, in separate letters dated February 7, 2020, Pfizer, X-GEN, and Fresenius requested that FDA withdraw approval of ANDAs 060733, 064153, and 065116, respectively, under § 314.150(d). Pfizer, X-GEN, and Fresenius also waived their opportunity for a hearing. Additionally, Akorn stated that it has never launched this product since its approval; X-GEN stated that it no longer manufactures bacitracin for injection under ANDA 064153; and Mylan stated that its product has not been in commercial distribution since 2012.

Therefore, for the reasons discussed above, which the applicants do not dispute in their letters requesting withdrawal of approval under § 314.150(d), FDA's approval of ANDAs 206719, 090211, 060733, 064153, 065116, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of Akorn's bacitracin for injection (50,000 units/vial), Mylan's bacitracin for injection (50,000 units/vial), Pfizer's bacitracin for injection (10,000 units/vial and 50,000 units/vial), X-GEN's bacitracin for injection (50,000 units/vial), or Fresenius's bacitracin for injection (50,000 units/vial) into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: March 1, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-05105 Filed 3-11-21; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0279]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Marketing; Administrative Procedures, Policies, and Requirements

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with prescription drug marketing under the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992.

**DATES:** Submit either electronic or written comments on the collection of information by May 11, 2021.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 11, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 11, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### 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-2011-N-0279 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug Marketing; Administrative Procedures, Policies, and Requirements." 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." The Agency 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