4164-01-P

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DATES: Approval is withdrawn as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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.

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: 3/11/2021 8:45 am; Publication Date: 3/12/2021]