4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-P-0038]

Determination That CUBICIN (Daptomycin) Powder for Injection, 250 Milligrams/Vial and 500 Milligrams/Vial, and CUBICIN RF (Daptomycin) Powder for Injection, 500 Milligrams/Vial, Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CUBICIN (daptomycin) Powder for Injection, 250 milligrams (mg)/vial and 500 mg/vial, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for daptomycin powder for injection, 250 mg/vial and 500 mg/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Tereza Hess, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6221, Silver Spring, MD 20993-0002, 202-768-5659, tereza.hess@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial, initially approved on September 12, 2003, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, initially approved on July 6, 2016, are the subjects of NDA 021572, held by Cubist Pharmaceuticals, LLC. CUBICIN and CUBICIN RF are indicated for treatment of complicated skin and skin structure infections in adult and pediatric patients (1 to 17 years of age), and *Staphylococcus aureus* bloodstream infections (bacteremia) in adult patients including those with right-sided infective endocarditis. CUBICIN is also indicated for treatment of *S. aureus* bloodstream infections (bacteremia) in pediatric patients (1 to 17 years of age).

CUBICIN (daptomycin) Powder for Injection, 250 mg/vial is currently listed in the "Discontinued Drug Product List" section of the Orange Book. In a letter dated June 22, 2021, Cubist Pharmaceuticals, LLC notified FDA that CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In a letter dated March 30, 2022, Cubist Pharmaceuticals, LLC notified FDA that CUBICIN (daptomycin) Powder for Injection,

500 mg/vial was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated January 3, 2023 (Docket No. FDA-2023-P-0038), under 21 CFR 10.30, requesting that the Agency determine whether CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial strengths, these strengths have also been discontinued. On our own initiative, we have also determined whether these strengths were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these drug products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CUBICIN (daptomycin) Powder for Injection, 250 mg/vial and 500 mg/vial, and CUBICIN RF (daptomycin) Powder for Injection, 500 mg/vial, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to these drug products may be approved by the Agency as long as they meet all other legal and

regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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