4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-P-4523]

Determination That Potassium Chloride in 5% Dextrose and 0.225% Sodium Chloride Injection, 5 Milliequivalents, 10 Milliequivalents, 15 Milliequivalents, 20 Milliequivalents, 30 Milliequivalents, and 40 Milliequivalents, in Plastic Containers, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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Administration (FDA or Agency) has determined that the potassium chloride drug products listed in this notice were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) that refer to these drug products, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Linda Jong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6288, Silver Spring, MD 20993-0002, 301-796-3977, Linda.Jong@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed

drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

The drug products listed in table 1 of this notice are no longer being marketed. All the products listed in table 1 are the subject of NDA 018365, held by ICU Medical, Inc., and initially approved on May 29, 1980. The products are indicated in patients requiring parenteral administration of potassium chloride with minimal carbohydrate calories and sodium chloride.

Table 1

Drug	Dosage Form/Route	Strength
Potassium Chloride (5 milliequivalents (mEq)) in 5% dextrose and 0.225% sodium chloride, in plastic container	Injectable/Injection	5 grams (g)/100 milliliters (mL); 74.5 milligrams (mg)/100 mL; 225 mg/100 mL

Drug	Dosage Form/Route	Strength
Potassium Chloride (5 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container	Do.	5 g/100 mL; 149 mg/100 mL; 225 mg/100 mL
Potassium Chloride (10 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container	Do.	5 g/100 mL; 74.5 mg/100 mL; 225 mg/100 mL
Potassium Chloride (10 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container	Do.	5 g/100 mL; 149 mg/100 mL; 225 mg/100 mL
Potassium Chloride (15 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container	Do.	5 g/100 mL; 224 mg/100 mL; 225 mg/100 mL
Potassium Chloride (20 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container	Do.	5 g/100 mL; 298 mg/100 mL; 225 mg/100 mL
Potassium Chloride (30 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container	Do.	5 g/100 mL; 224 mg/100 mL; 225 mg/100 mL
Potassium Chloride (40 mEq) in 5% dextrose and 0.225% sodium chloride, in plastic container	Do.	5 g/100 mL; 298 mg/100 mL; 225 mg/100 mL

The products listed in table 1 are currently listed in the "Discontinued Drug Product List" section of the Orange Book. Fresenius Kabi USA, LLC, submitted a citizen petition dated September 26, 2019 (Docket No. FDA-2019-P-4523), under 21 CFR 10.30, requesting that the Agency determine whether the products listed in table 1 were withdrawn from sale for reasons of safety or effectiveness.

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 the potassium

chloride drug products listed in this notice were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that the potassium chloride drug products listed in this notice were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of the potassium chloride drug products listed in this notice 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 the potassium chloride drug products listed in this notice were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list the potassium chloride drug products listed in this notice, 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. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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