4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-P-1363]

Determination That SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (Sodium Chloride), Injectable, 234 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for sodium chloride, injectable, 234 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Faranda, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6213, Silver Spring, MD 20993-0002, 301-796-8767.

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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness.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.

SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, is the subject of NDA 019329, held by Abraxis Pharmaceutical Products, and initially approved on April 22, 1987. SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER is indicated for use in patients who have special problems of sodium electrolyte intake or excretion, and for the treatment of sodium chloride and water deficiencies, which commonly occur in many diseases.

In a letter dated January 18, 1996, the original NDA holder, Fujisawa USA, Inc., notified FDA that SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride),

injectable, 234 mg/mL, was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Gordon Johnston Regulatory Consultants, LLC, submitted a citizen petition dated May 25, 2016 (Docket No. FDA-2016-P-1363), under 21 CFR 10.30, requesting that the Agency determine whether SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, was 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 SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SODIUM CHLORIDE 23.4% IN PLASTIC CONTAINER (sodium chloride), injectable, 234 mg/mL, 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 this drug product 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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: December 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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