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Dated: August 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18313 Filed 8–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–P–0964 and FDA–2018–P–0967]

Determination That PLASMA–LYTE M AND DEXTROSE 5% and PLASMA LYTE 148 AND DEXTROSE 5% Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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 PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 milligrams (mg)/100 milliliters (mL); dextrose, 5 grams (g)/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) and PLASMA LYTE 148 AND DEXTROSE 5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 mL) were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Heather A. Dorsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–3601.

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.

PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 mg/100 mL; dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) is the subject of NDA 017390, held by Baxter Healthcare Corp., and initially approved on February 1, 1979. PLASMA LYTE 148 AND DEXTROSE 5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 mL) is the subject of NDA 017451, held by Baxter Healthcare Corp., and initially approved on February 2, 1979. PLASMA LYTE M AND DEXTROSE 5% is indicated as a source of water, electrolytes, and calories or as an alkalinizing agent. PLASMA LYTE 148 AND DEXTROSE 5% is indicated as a source of water, electrolytes, and calories, or as an alkalinizing agent.

PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 mg/100 mL; dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) and PLASMA LYTE 148 AND DEXTROSE

5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 mL) are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of October 13, 2015 (80 FR 61426), FDA announced that it was withdrawing approval of NDAs 017390 and 017451, effective November 12, 2015.

Fresenius Kabi USA, LLC, submitted two citizen petitions dated March 2, 2018 (Docket No. FDA–2018–P–0964), and March 5, 2018 (Docket No. FDA–2018–P–0967), under 21 CFR 10.30, requesting that the Agency determine whether PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 mg/100 mL; dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) and PLASMA LYTE 148 AND DEXTROSE 5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 mL) were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 mg/100 mL; dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) and PLASMA LYTE 148 AND DEXTROSE 5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 mL) were not withdrawn 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 PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 mg/100 mL; dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) and PLASMA LYTE 148 AND DEXTROSE 5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 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 these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 mg/100 mL; dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) and PLASMA LYTE 148 AND DEXTROSE 5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 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 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 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18311 Filed 8–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0101]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug User Fee Cover Sheet; Form FDA 3397

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 the information collection requirements relating to the Prescription Drug User Fee Cover Sheet, Form FDA 3397, that must be submitted along with certain drug and biological product applications.

DATES: Submit either electronic or written comments on the collection of information by October 23, 2018.

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 October 23, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 23, 2018. 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