other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 16, 2010.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0412]

Determination That HalfLytely and Bisacodyl Tablets Bowel Prep Kit (Containing 4 Bisacodyl Delayed Release Tablets, 5 Milligrams) Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (polyethylene glycol (PEG) 3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 4 bisacodyl delayed release tablets, 5 milligrams (mg) (20-mg bisacodyl)) was withdrawn from sale for reasons of safety or effectiveness. The agency will not accept or approve abbreviated new drug applications (ANDAs) for bowel prep kits containing PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 4 bisacodyl delayed release tablets, 5 mg.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, 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 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved 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 only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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 generally known 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). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

On July 15, 2008, FDA received a citizen petition (Docket No. FDA–2008–P–0412), submitted under 21 CFR 10.30, from Foley & Lardner LLP. The petition requests that the agency determine whether HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 4 bisacodyl delayed release tablets, 5 mg) (HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl)), manufactured by Braintree Laboratories, Inc. (Braintree), was withdrawn from sale for reasons of safety or effectiveness.

HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) (NDA 21–551) was approved on May 10, 2004. HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) was indicated for the cleansing of the colon as preparation for colonoscopy in adults. Braintree informed FDA that it ceased to manufacture and market HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) as of September 25, 2007. The drug product was then moved to the "Discontinued Drug Product List" section of the Orange Book.

FDA has reviewed its records concerning the withdrawal of HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl). FDA has also independently evaluated relevant literature, data from clinical trials, and reports of possible postmarketing adverse events. FDA has determined, under § 314.161, that HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) was withdrawn from sale for reasons of safety or effectiveness.

Braintree discontinued this product containing a total dose of 20 milligrams of bisacodyl from sale after receiving approval from FDA on September 24, 2007, for HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 2 bisacodyl delayed release tablets, 5 mg (10-mg bisacodyl)). The data available from multiple clinical studies show that the HALFLYTLEY AND BISACODYL TABLETS BOWL PREP KIT (10-mg bisacodyl) has comparable effectiveness to the 20-mg product and has a safety advantage over the 20-mg product because there is less nausea and abdominal cramping in the patients treated with the 10-mg product. Furthermore, the 20-mg product may be associated with ischemic colitis.

FDA has also reviewed the latest approved labeling for the 20-mg product and has determined that it would need to be updated with additional safety information if Braintree were to reintroduce the 20-mg product to the market. FDA has determined that additional clinical studies of safety and efficacy would be necessary before HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (20-mg bisacodyl) could be considered for reintroduction to the market. Accordingly, the agency will remove HALFLYTELY AND BISACODYL TABLETS BOWEL PREP KIT (PEG–3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and 4 bisacodyl delayed release tablets, 5 mg) from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Dated: March 15, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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