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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1702]

Baxter Healthcare Corporation et al.; Withdrawal of Approval of One New Drug Application and Four Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of one new drug application (NDA) for Ondansetron (ondansetron hydrochloride (HCl)) Injection, USP in PL 2408 Plastic Container, 32 milligrams (mg) in 50 milliliters (mL), single intravenous (IV) dose, and four abbreviated new drug applications (ANDAs) for ondansetron HCl and Dextrose in 32 mg single IV doses. The holders of these applications have voluntarily requested that FDA withdraw approval of their applications and have waived their opportunity for a hearing.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Emily Helms Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6280, Silver Spring, MD 20993-0002, 301-796-3381.

SUPPLEMENTARY INFORMATION: On June 29, 2012, FDA issued a Drug Safety Communication to notify health care professionals that the 32 mg, single IV dose of ondansetron HCl, indicated for prevention of nausea and vomiting associated with initial and repeat courses

of emetogenic cancer chemotherapy in adult patients, should be avoided due to the risk of a specific type of irregular heart rhythm called QT interval prolongation, which can lead to Torsades de Pointes, an abnormal, potentially fatal heart rhythm. Subsequently, FDA contacted the holders of the following applications and informed them that the Agency believes that in light of the safety concern associated with ondansetron HCl in the 32 mg, single IV dose, the following drug products should be removed from the market:

Application Number	Drug	Applicant
NDA 021915	Ondansetron Hydrochloride Injection, USP premix in Intravia Plastic Container	Baxter Healthcare Corporation (Baxter), 32650 N. Wilson Rd., Round Lake, IL 60073
ANDA 077348	Ondansetron Hydrochloride and Dextrose in Plastic Container	Hospira, Inc. (Hospira), 275 North Field Dr., Department 389, Bldg. H2-2, Lake Forest, IL 60045
ANDA 077480	Ondansetron Hydrochloride and Dextrose in Plastic Container	Teva Pharmaceuticals USA (Teva), 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677
ANDA 078291	Ondansetron Hydrochloride and Dextrose in Plastic Container	Bedford Labs (Bedford), 300 Northfield Rd., Bedford, OH 44146
ANDA 078308	Ondansetron Hydrochloride and Dextrose in Plastic Container	Claris Lifesciences Ltd. (Claris), 2325 Camino Vida Roble, Suite A, Carlsbad, CA 92011

As described in this document, the application holders agreed to voluntarily remove their respective 32 mg, single IV dose ondansetron products from the market, and requested that FDA withdraw approval of their respective applications (listed in the preceding table) under § 314.150(d) (21 CFR 314.150(d)). On December 4, 2012, FDA issued an updated Drug Safety Communication alerting health care professionals that these products would be removed from the market because of their potential for serious cardiac risks.

Baxter's Ondansetron (ondansetron HCl) Injection, USP in PL 2408 Plastic Container, 32 mg/50 mL, single IV dose, was approved in NDA 021915 on December 27, 2006. In a letter

dated November 27, 2012, Baxter requested withdrawal of NDA 021915 under 21 CFR 314.150(d), and waived its opportunity for a hearing provided under § 314.150(a). In a letter dated September 5, 2012, Baxter notified FDA that the product was being discontinued. In a contemporaneous notice, FDA is announcing its determination that the product was withdrawn from sale for reasons of safety or effectiveness and that FDA will not accept or approve ANDAs that refer to this drug product.

Hospira's ondansetron HCl Injection 32 mg/50 mL, single IV dose was approved in ANDA 077348 on February 1, 2007. In a letter dated January 31, 2013, Hospira requested withdrawal of ANDA 077348 under 21 CFR 314.150(d), and waived its opportunity for a hearing provided under § 314.150(a).

Teva's ondansetron HCl Injection 32 mg/50 mL, single IV dose was approved in ANDA 077480 on November 22, 2006. In a letter dated November 20, 2012, Teva requested withdrawal of ANDA 077480 under 21 CFR 314.150(d), and waived its opportunity for a hearing provided under § 314.150(a).

Bedford's ondansetron HCl Injection 32 mg/50 mL, single IV dose was approved in ANDA 078291on April 13, 2009. In a letter dated April 4, 2014, Bedford requested withdrawal of ANDA 078291, under 21 CFR 314.150(d), and waived its opportunity for a hearing provided under § 314.150(a).

Claris's ondansetron HCl Injection 32 mg/50 mL, single IV dose, was approved in ANDA 078308 on March 17, 2008. In a letter dated November 16, 2012, through its U.S. agent, CUSTOpharm, Inc., Claris requested withdrawal of ANDA 078308 under 21 CFR 314.150(d), and waived its opportunity for a hearing provided under § 314.150(a).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and 21 CFR 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of the applications listed in the table of this document, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)). The Agency will remove these products from the list of drug products with effective approvals published in FDA's "Approved Drug Products With Therapeutic Equivalence Evaluations," generally referred to as the "Orange Book."

Dated: June 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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