4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0869]

Pfizer, Inc.; Withdrawal of Approval of a New Drug Application for BEXTRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for BEXTRA (valdecoxib) 10 milligram (mg) and 20 mg Tablets, held by Pfizer, Inc. (Pfizer), 235 East 42nd St., New York, NY 10017-5755. Pfizer has voluntarily requested that approval of this application be withdrawn and has waived its opportunity for a hearing.

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

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6250, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: FDA approved BEXTRA (valdecoxib) 10 mg and 20 mg Tablets on November 16, 2001. BEXTRA is indicated for relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis and for the treatment of primary dysmenorrhea. On April 7, 2005, FDA announced that it had concluded that the overall risk versus benefit profile of BEXTRA was unfavorable and that it had asked Pfizer to voluntarily withdraw BEXTRA from the market. Pfizer agreed and voluntarily suspended all sales and marketing of BEXTRA on July 21, 2005. In letters dated May 27, 2011, August 8, 2011, and October 31,

2011, Pfizer requested that FDA withdraw approval of NDA 21-341 for BEXTRA. In the letter dated October 31, 2011, Pfizer waived any opportunity for a hearing otherwise provided under 21 CFR 314.150 (§ 314.150). In FDA's letter of November 9, 2011, responding to Pfizer's letters dated May 27, 2011, August 8, 2011, and October 31, 2011, the Agency acknowledged Pfizer's request to withdraw approval of BEXTRA under § 314.150(d) and waive its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 21-341, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product 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)).

Dated: July 30, 2013.

Janet Woodcock,

Director,

Center for Drug Evaluation and Research.

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