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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. [FDA-2012-N-0690]

Wyeth Pharmaceuticals, Inc.; Withdrawal of Approval of a New Drug Application for DURACT Capsules

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 DURACT (bromfenac sodium) Capsules, held by Wyeth Pharmaceuticals, Inc. (Wyeth), P.O. Box 8299, Philadelphia, PA 19101-8299. Wyeth, now a part of Pfizer, Inc., has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

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

FOR FURTHER INFORMATION CONTACT:

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Center for Drug Evaluation and Research,

Food and Drug Administration,

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Silver Spring, MD 20993-0002,

301-796-3601.

SUPPLEMENTARY INFORMATION:

In June 1998, Wyeth voluntarily withdrew DURACT (bromfenac sodium) Capsules from the market. DURACT (bromfenac sodium) Capsules, a nonsteroidal anti-inflammatory drug indicated for the short-term management of acute and chronic pain, were withdrawn from the market after FDA and Wyeth received postmarketing reports of rare, severe liver toxicity in patients who took DURACT for periods of time beyond that recommended in the labeling.

In a letter dated December 9, 2011, Wyeth requested that FDA withdraw approval of NDA 20-535, DURACT (bromfenac sodium) Capsules, under § 314.150(d) (21 CFR 314.150(d)). In that letter, Wyeth also 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 § 314.150(d), and under authority delegated by the Commissioner of Food and Drugs to the Director, Center for Drug Evaluation and Research, approval of NDA 20-535, and all amendments and supplements thereto, is withdrawn (see DATES).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: June 21, 2012.

Janet Woodcock,
Director,
Center for Drug Evaluation and Research.

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