4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0559]

Eli Lilly and Co.; Withdrawal of Approval of a New Drug Application for ORAFLEX

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 ORAFLEX (benoxaprofen) Tablets, held by Eli Lilly and Co. (Lilly), Lilly Corporate Center, Indianapolis, IN 46285. Lilly has voluntarily requested that approval of this application be withdrawn, and has waived its opportunity for a hearing.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:

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SUPPLEMENTARY INFORMATION:

On April 19, 1982, FDA approved ORAFLEX (benoxaprofen) Tablets, a nonsteroidal anti-inflammatory drug indicated for the treatment of arthritis. On August 4, 1982, Lilly

voluntarily withdrew ORAFLEX (benoxaprofen) Tablets from the market because of postmarketing reports of severe liver toxicity in patients who took ORAFLEX. In a letter dated February 6, 2013, Lilly requested that FDA withdraw approval of NDA 18-250 for ORAFLEX (benoxaprofen) Tablets under § 314.150(d) (21 CFR 314.150(d)). In that letter, Lilly waived any opportunity for a hearing otherwise provided under § 314.150(a). In FDA's letter of February 15, 2013, the Agency acknowledged Lilly's agreement to permit FDA to withdraw approval of ORAFLEX (benoxaprofen) Tablets under § 314.150(d) and waive its opportunity for a hearing.

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Center for Drug Evaluation and Research, approval of NDA 18-250, and all amendments and supplements thereto, is withdrawn (see DATES).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: May 28, 2013.

Janet Woodcock,

Director,

Center for Drug Evaluation and Research.

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