4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0494]

Pfizer, Inc.; Withdrawal of Approval of Familial Adenomatous Polyposis Indication for CELEBREX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the familial adenomatous polyposis (FAP) indication for CELEBREX (celecoxib) Capsules held by Pfizer, Inc. (Pfizer), 235 East 42nd St., New York, NY 10017-5755. Pfizer has voluntarily requested that approval of this indication be withdrawn, thereby waiving its opportunity for a hearing.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 the FAP indication for CELEBREX on December 23, 1999, under the Agency's accelerated approval regulations, 21 CFR part 314,

subpart H. In addition to FAP, CELEBREX is indicated for the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis in patients 2 years and older, ankylosing spondylitis, primary dysmenorrhea, and for the management of acute pain in adults. Withdrawal of approval of the FAP indication does not affect any other approved indication for CELEBREX. On February 2, 2011, FDA requested that Pfizer voluntarily withdraw the FAP indication for CELEBREX (celecoxib) Capsules from the market because the postmarketing study intended to verify clinical benefit and required as a condition of approval under subpart H was never completed. In a letter dated February 3, 2011, Pfizer requested that FDA withdraw the FAP indication for CELEBREX (celecoxib) Capsules from the market. In that letter, Pfizer waived any opportunity for a hearing otherwise provided under 21 CFR 314.150 and 314.530, and noted that withdrawal of the FAP indication was not "due to any new efficacy or safety data." In FDA's letter of February 4, 2011, the Agency acknowledged Pfizer's agreement to permit FDA to withdraw the FAP indication for CELEBREX (celecoxib) Capsules under 21 CFR 314.150(d) and waive its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic 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 FAP indication for CELEBREX (celecoxib) Capsules is withdrawn (see DATES).

Dated: May 4, 2012.

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

[FR Doc. 2012-13900 Filed 06/07/2012 at 8:45 am; Publication Date: 06/08/2012]