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 Pfizer has voluntarily requested that approval of this indication be withdrawn, thereby waiving its opportunity for a hearing.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 June 8, 2012.
FOR FURTHER INFORMATION CONTACT:
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 approval of 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Director, Center for Drug Evaluation and Research, approval of the FAP indication for CELEBREX (celecoxib) Capsules is withdrawn (see DATES).
Janet Woodcock, Director, Center for Drug Evaluation and Research.

DEPARTMENT OF HOMELAND SECURITY
U.S. Citizenship and Immigration Services
Agency Information Collection Activities: Form I–102; Revision of an Existing Information Collection; Comment Request
SUMMARY: The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the Federal Register on February 28, 2012 at 77 FR 12070, allowing for a 60-day public comment period. USCIS did not receive any comments for this information collection.
The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 9, 2012. This process is conducted in accordance with 5 CFR 1320.10.
Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Management and Budget (OMB) USCIS Desk Officer. Comments may be submitted to: USCIS, Chief Regulatory Coordinator, Regulatory Coordination Division, Office of Policy and Strategy, Clearance.