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 Pfizer has voluntarily requested that approval of this indication be withdrawn, thereby waiving its opportunity for a hearing.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: 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.”

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Director, Center for Drug Evaluation and Research, approval of the FAP indication for CELEBREX (celecoxib) Capsules is withdrawn.

Effective June 8, 2012.
Office, 20 Massachusetts Avenue, Washington, DC 20529. Comments may also be submitted to DHS via email at uscisfrcomment@dhs.gov, to the OMB USCIS Desk Officer via facsimile at 202–395–5806 or via email at oira_submission@omb.eop.gov.

When submitting comments by email please make sure to add OMB Control Number 1615–0079 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) Type of Information Collection: Revision of an existing information collection.
(2) Title of the Form/Collection: Application for Replacement/Initial Nonimmigrant Arrival-Departure Document.
(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or households. Nonimmigrants temporarily residing in the United States use this form to request a replacement of their arrival evidence document.
(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 17,700 responses at .416 hours (25 minutes) per response.
(6) An estimate of the total public burden (in hours) associated with the collection: 7,363.2 annual burden hours.

If you need a copy of the information collection instrument, please visit the Web site at: http://www.regulations.gov/.

We may also be contacted at: USCIS, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

Laura Dawkins,
Acting Chief Regulatory Coordinator,

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BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–590, Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form I–590, Registration for Classification as Refugee.

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 March 12, 2012, at 77 FR 14535, 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 Coordination Division, Office of Policy and Strategy, Clearance Office, 20 Massachusetts Avenue NW., Washington, DC 20529. Comments may also be submitted to DHS via email uscisfrcomment@dhs.gov, and to the OMB USCIS Desk Officer via facsimile at 202–395–5806 or via email at oira_submission@omb.eop.gov.

When submitting comments by email please make sure to add OMB Control Number 1615–0068 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) Type of Information Collection: Extension of a currently approved information collection.
(2) Title of the Form/Collection: Registration for Classification as Refugee.
(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or Households. Form I–590 provides a uniform method for applicants to apply for refugee status and contains the information needed for USCIS to adjudicate such applications.
(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 100,000 responses at .583 hours (35 minutes) per response.
(6) An estimate of the total public burden (in hours) associated with the collection: 58,300 annual burden hours.