

location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section of this document) on or before October 15, 2012, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:15 a.m. on October 30, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 4, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 5, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristina Toliver at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 4, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-13868 Filed 6-7-12; 8:45 am]

**BILLING CODE 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 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." 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 6-7-12; 8:45 am]

**BILLING CODE 4160-01-P**

## 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**

**ACTION:** 30-Day Notice of Information Collection Under Review; Form I-102, Application for Replacement/Initial Nonimmigrant Arrival-Departure Document.

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

Office, 20 Massachusetts Avenue, Washington, DC 20529. Comments may also be submitted to DHS via email at [uscisfrcomment@dhs.gov](mailto:uscisfrcomment@dhs.gov), to the OMB USCIS Desk Officer via facsimile at 202-395-5806 or via email at [oir\\_submission@omb.eop.gov](mailto:oir_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.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-102; U.S. Citizenship and Immigration Services (USCIS).

(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, 20 Massachusetts Avenue NW., Washington, DC 20529, Telephone number 202-272-1470.

Dated: May 23, 2012.

**Laura Dawkins,**

*Acting Chief Regulatory Coordinator, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.*

[FR Doc. 2012-13799 Filed 6-7-12; 8:45 am]

**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](mailto:uscisfrcomment@dhs.gov), and to the OMB USCIS Desk Officer via facsimile at 202-395-5806 or via email at [oir\\_submission@omb.eop.gov](mailto:oir_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.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-590; U.S. Citizenship and Immigration Services (USCIS).

(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.