DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2012–N–0548]

Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Drug Safety and Risk Management Advisory Committee.

General Function of the Committee:
To provide advice and recommendations to the Agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on October 29, 2012, from 8 a.m. to 5 p.m. and October 30, 2012, from 8 a.m. to 3 p.m.

ADDRESSES: FDA is opening a docket for public comment on this meeting. The docket number is FDA–2012–N–0548. The docket will open for public comment on June 8, 2012. The docket will close on November 6, 2012. Interested persons may submit either electronic or written comments regarding this meeting. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments received will be posted without change, including any personal information provided. It is only necessary to send one set of comments.

Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments received on or before October 15, 2012, will be provided to the committee before the meeting.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1003), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/default.htm; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–3602. Submit comments to Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 10903 New Hampshire Ave., Bldg. 51, Rm. 20852, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: In FR Doc. 2012–26017 in the Federal Register of Wednesday, May 2, 2012, the following correction is made:

1. On page 26017, in the third column, in the last paragraph, “U.S. Patent Nos. 5,795,685 and 7,276,480” is corrected to read “U.S. Patent Nos. 5,795,865 and 7,276,480.”


Jane A. Axelrad,
Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2012–13902 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:

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.

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 1207.10.

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), 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...