

requirements under the FD&C Act relating to drug products. This conclusion was based on the fact that Dr. Justice had legal and professional obligations to ensure that he submitted accurate medical claims for procedures he performed, as well as administering medicines that were appropriate for his patients' condition, which he knowingly and willingly disregarded, as well as the fact that Dr. Justice intentionally billed for different FDA-regulated drug products than what he wrote prescriptions for. Therefore, FDA had reason to believe that, if Dr. Justice were to provide services to a person that has an approved or pending drug application, he may violate requirements under the FD&C Act relating to drug products. The proposal offered Dr. Justice an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on March 29, 2012. Dr. Justice failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Glen R. Justice has been convicted of five counts of a felony under Federal law for conduct involving health care fraud, and, on the basis of the conviction and other information, finds that Dr. Justice has demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products.

As a result of the foregoing finding, Dr. Justice is debarred for 25 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**) (see sections 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise

uses the services of Dr. Justice, in any capacity during Dr. Justice's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Justice provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Justice during his period of debarment (section 306(c)(1)(A) of the FD&C Act).

Any application by Dr. Justice for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA-2011-N-0860 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 22, 2012.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012-16600 Filed 7-6-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0690]

Wyeth Pharmaceuticals, Inc.; Withdrawal of Approval of a New Drug Application for DURACT Capsules

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for DURACT (bromfenac sodium) Capsules, held by Wyeth Pharmaceuticals, Inc. (Wyeth), P.O. Box 8299, Philadelphia, PA 19101-8299. Wyeth, now a part of Pfizer, Inc., has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

DATES: Effective July 9, 2012.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In June 1998, Wyeth voluntarily withdrew DURACT (bromfenac sodium) Capsules from the market. DURACT (bromfenac sodium) Capsules, a nonsteroidal anti-inflammatory drug indicated for the short-term management of acute and chronic pain, were withdrawn from the market after FDA and Wyeth received postmarketing reports of rare, severe liver toxicity in patients who took DURACT for periods of time beyond that recommended in the labeling.

In a letter dated December 9, 2011, Wyeth requested that FDA withdraw approval of NDA 20-535, DURACT (bromfenac sodium) Capsules, under § 314.150(d) (21 CFR 314.150(d)). In that letter, Wyeth also waived its opportunity for a hearing, provided under § 314.150(a).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner of Food and Drugs to the Director, Center for Drug Evaluation and Research, approval of NDA 20-535, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: June 21, 2012.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2012-16597 Filed 7-6-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Translational Grant Applications Review.

Date: July 23, 2012.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Chevy Chase Pavilion, 4300 Military Road, Washington, DC 20015.

Contact Person: Daniel R. Kenshalo, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301-451-2020, kenshalod@nei.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Clinical Planning and Data Analysis.

Date: July 25-26, 2012.

Time: 8:30 a.m. to 9 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Anne E. Schaffner, Ph.D., Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301-451-2020, aes@nei.nih.gov.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Clinical Trials.

Date: July 31, 2012.

Time: 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Anne E. Schaffner, Ph.D., Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301-451-2020, aes@nei.nih.gov.

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Training Grants.

Date: August 6, 2012.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, 7301 Waverly Street, Bethesda, MD 21045.

Contact Person: Brian Hoshaw, Ph.D., Scientific Review Officer, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane, Suite 1300, MSC 9300, 301-451-2020, hoshawb@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: June 28, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-16678 Filed 7-6-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel Age, Gene/Environment Susceptibility—Reykjavik Study Continuation.

Date: July 24, 2012.

Time: 11 a.m. to 12:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Alexander Parsadonian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2c/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-496-9666, parsadonian@nia.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Aging Special Emphasis Panel, Genes and Longevity in Humans.

Date: July 27, 2012.

Time: 12:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2C212, MSC-9205, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-402-7707, elainelewis@nia.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: June 29, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-16676 Filed 7-6-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Ancillary Studies to the Intestinal Stem Cells Consortium.

Date: July 30, 2012.

Time: 12 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Maria E. Davila-Bloom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7637, davila-bloom@extra.niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)