

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,