DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0529]

Pfizer, Inc.; Withdrawal of Approval of a New Drug Application

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 REZULIN (troglitazone) Tablets held by Pfizer, Inc., 235 East 42d Street, New York, NY 10017. Pfizer has voluntarily withdrawn this NDA because the product is no longer marketed, thereby waiving its opportunity for a hearing.

DATES: Effective January 10, 2003.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In a letter dated May 1, 2002, Pfizer, Inc., requested that FDA withdraw under § 314.150(d) (21 CFR 314.150(d)), NDA 20–720 for REZULIN (troglitazone) Tablets, stating that The Warner-Lambert Co., which Pfizer acquired in June 2000, discontinued marketing the product in March 2000. REZULIN (troglitazone) Tablets, a treatment for type 2 diabetes, was voluntarily withdrawn after review of safety data showed that the drug is more toxic to the liver than two other more recently approved drugs that offer a similar benefit. Pfizer waived its opportunity for a hearing, provided under § 314.150(a) and (b).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.105(a)), approval of the NDA 20–720, and all amendments and supplements thereto, is withdrawn. 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 act (21 U.S.C. 355(a) and 331(d)).

Dated: December 16, 2002.

Jane Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03–493 Filed 1–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Medical Device User Fee Rates for Fiscal Year 2003 and Interim Procedures; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of November 21, 2002 (67 FR 70228). The document announced the rates and interim procedures for medical device user fees for fiscal year (FY) 2003. The document was inadvertently published with confusing language regarding the fee that must be paid by a small business that submits a 510(k) premarket notification for FDA review during FY 2003. The document intended to state that all 510(k)s submitted for FDA review during FY 2003 are subject to a standard fee of $2,187, and that all submitters who are subject to a fee, including a small business, are required to pay this fee. This document corrects that error.

ADDRESSES: Persons with access to the Internet may obtain further information on the Medical Device User Fee and Modernization Act of 2002 at http://www.fda.gov/cdrh/mdufma or http://www.fda.gov/cber/mdufma/mdufma.htm.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management and Systems (HFA–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION: In FR Doc. 02–29572, appearing on page 70228 in the **Federal Register** of Thursday, November 21, 2002, the following corrections are made:

1. On page 70228, in the third column, under ''III. Fee Calculations for FY 2003,'' the fourth sentence is corrected to read ''Table 1 of this document summarizes the types of applications that are subject to a fee, the full fee amount expressed as a percent of the fee for a PMA, the full (standard) fee for FY 2003, and the fee that may be paid by a qualified small business.''

2. On page 70229, in the second column, the first full sentence is corrected to read ''For premarket notification submissions, a small business will pay the full (standard) fee of $2,187.''

3. On page 70229, in table 1, in the third column, in the last row, ''2,187'' is corrected to read ''2,187[1]''.

4. On page 70229, under table 1, add the following footnote to read as follows: ''[1]A small business will pay the full (standard) fee of $2,187 for a premarket notification submitted to FDA during FY 2003. A small business fee, set at 80 percent of the standard 510(k) fee, will be available beginning FY 2004.''

Dated: January 6, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–494 Filed 1–9–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; NIH Intramural Research Training Award, Program Application

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on Friday, October 4, 2002, page 62253 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: NIH Intramural Research Training Award, Program Application; Type of Information Collection Request: Revision of OMB No. 0925–0299; Expiration date 03/31/2003; Need and Use of Information Collection: The proposed information collection activity is for the purpose of collecting data related to the availability of Training Fellowships under the NIH Intramural Research Training Award Program. This information must be submitted in order to receive due consideration for an award and will be used to determine the eligibility and quality of potential awardees. Frequency of Response: On occasion. Affected Public: Individuals seeking Intramural Training award

opportunities. Type of Respondents: Postdoctoral, Predoctoral, Post-baccalaureate, Technical, and Student IRTA applicants.

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Type of respondent	Estimated number for respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Postdoctoral IRTA	1,375	1.00	1.00	1,375
Predoctoral	306	1.00	1.00	306
Postbaccalaureate	793	1.00	1.00	793
Technical IRTA	83	1.00	1.00	83
Student IRTA	3,800	1.00	1.00	3,800
References for all IRTA categories	15,188	1.00	0.33	5,012
Total	21,545	1.00	0.5276862	11,369

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and the clarity of information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Edie Bishop, Personnel Management Specialist, Office of Human Resources, OD, NIH, Building 31, Room B3C07, 31 Center Drive MSC. 2203, Bethesda, MD, 20892–2203, or call non-toll-free number (301) 496–1443, or E-mail your request, including your address to: *Bishope@od.nih.gov*.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: January 3, 2003.

Frederick C. Walker,

Acting Director, Office of Human Resources.

[FR Doc. 03–439 Filed 1–9–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Allergy and Infectious Diseases Special Emphasis Panel.

Date: January 28–30, 2003.

Time: January 28, 2003, 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Time: January 29, 2003, 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Time: January 30, 2003, 8:30 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW. Washington, DC 20007.

Contact Person: Nancy B. Saunders, PhD., Scientific Review Administrator, Division of Extramural Activities, NIAID, NIH, Scientific Review Program, Room 2217, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550, *ns120v@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 3, 2003.

Anna Snouffer.

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–440 Filed 1–9–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals and the discussions could disclose confidential