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 Pfizer has voluntarily withdrawn this NDA because the product is no longer marketed, thereby waiving its opportunity for a hearing.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 REZULIN (troglitazone) Tablets, a treatment for type 2 diabetes, was voluntarily withdrawn after review of safety data showed that the drug is more toxic to the liver than two other more recently approved drugs that offer a similar benefit.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Evaluation and Research (21 CFR 5.105(a)), approval of the NDA 20–720, and all amendments and supplements thereto, is withdrawn.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