TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Total Hours
600.14	3486	147	2.73	401	2.0	802
606.171 [2]	3486	194	169.89	32,958	2.0	65,916
606.171 [3]	3486	6,210	1.50	9,311	2.0	18,622
	3486A [4]	6,551	0.33	2,133	0.5	1,067
Total						86,407

[1] There are no capital costs or maintenance costs associated with this collection of information.
[2] Licensed manufacturers of human blood and blood components, including Source Plasma.
[3] Unlicensed registered blood establishments and transfusion services (1,230 + 4,980 = 6,210).
[4] Five percent of the total annual responses to CBER (42,653 x 0.05 = 2,133).

Dated: January 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–1415 Filed 1–29–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0105]

James T. Kimball; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Mr. James T. Kimball's request for a hearing and is issuing a final order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. James T. Kimball from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Kimball was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the act. In addition, Mr. Kimball has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is effective January 30, 2007.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION:

I. Background

On May 24, 2000, a jury found Mr. Kimball guilty of one count of conspiring to commit offenses against the United States and the Florida Department of Health, a Federal felony offense under 18 U.S.C. 371; six counts of distributing a misbranded drug into interstate commerce, a Federal felony offense under 21 U.S.C. 331(a); and one count of making a false statement in a matter within the jurisdiction of a Federal agency, a Federal felony offense under 18 U.S.C. 1001. On October 19, 2000, the U.S. District Court for the Middle District of Florida entered judgment and sentenced Mr. Kimball for these offenses.

The bases for these convictions were Mr. Kimball's knowing and willful participation, including conspiring, to violate Federal laws in connection with the distribution of a misbranded drug, deprenyl, into interstate commerce, and false statements he made to the U.S. Customs Service about shipments of deprenyl for export. The drug deprenyl was misbranded because it contained selegiline, the active ingredient of a prescription drug Eldepryl, but was dispensed without a prescription issued by a licensed practitioner.

As a result of these convictions, FDA served Mr. Kimball by certified letter on April 25, 2005,[1] a proposal to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The notice also offered Mr. Kimball an opportunity to request a hearing on the debarment proposal. The debarment proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Mr. Kimball was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the act.

The certified letter also informed Mr. Kimball that his request for a hearing could not rest upon mere allegations or denials, but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also informed Mr. Kimball that the only material issue of fact was whether he was convicted as alleged in the letter, and that the facts underlying his conviction are not at issue in this proceeding. Finally, the letter informed Mr. Kimball that if it conclusively appeared from the face of the information and factual analyses in his request for a hearing that there was no genuine and substantial issue of fact that precluded the order of debarment, FDA would enter summary judgment against him and deny his request for a hearing.

In a letter dated May 16, 2005, Mr. Kimball responded to the certified letter by requesting a hearing.

II. Denial of Hearing

In his May 16, 2005, request for a hearing, Mr. Kimball does not present any arguments or information to show why he should not be debarred. Mr. Kimball merely states that: (1) He ''was not convicted pursuant to the statements set forth in FDA's alleged notice'', (2) the allegations of his convictions are incorrect, and (3) his conviction does not mandate his debarment. Such statements do not create a basis for a hearing because hearings will not be granted on mere allegations, denials, or general

[1] The certified letter was mailed to the prison facility where records indicated that Mr. Kimball was incarcerated, and the return receipt was signed on April 25, 2005, by an employee at the facility. In his request for hearing, Mr. Kimball stated that he received the letter on May 5, 2005. The delivery dates do not alter the nature of Mr. Kimball's request for a hearing or our application of summary judgement in this matter.

descriptions of positions (see 21 CFR 12.24(b)(2)). Although FDA's proposal to debar Mr. Kimball explained that he had the opportunity to file a request for a hearing and then submit factual information within 60 days from receipt of the letter, Mr. Kimball did not submit any factual information. Mr. Kimball has failed to present any arguments or information to show why he should not be debarred. Therefore, FDA finds that Mr. Kimball has failed to identify any genuine and substantial issue of fact requiring a hearing. Accordingly, FDA denies Mr. Kimball's request for a hearing.

III. Findings and Order

Therefore, the Associate Commissioner for Regulatory Affairs, under section 306(a) of the act and under authority delegated to him, finds that Mr. James T. Kimball has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the act (section 306(a)(2)(B) of the act).

As a result of the foregoing findings, Mr. James T. Kimball is permanently debarred 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 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**) (sections 306(c)(1)(B) and (c)(2)(A)(iii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Kimball in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Kimball, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Kimball during his period of debarment.

Any application by Mr. Kimball for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 2005N–0105 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: January 22, 2007.

Margaret O'K. Glavin,

Associate Commissioner for Regulatory Affairs.

[FR Doc. E7–1416 Filed 1–29–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0029]

Indevus Pharmaceuticals, 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 REDUX (dexfenfluramine hydrochloride (HCl)) Capsules held by Indevus Pharmaceuticals, Inc. (Indevus), 33 Hayden Ave., Lexington, MA 02421–7971. Indevus has requested that approval of this application be withdrawn because the product is no longer marketed, thereby waiving its opportunity for a hearing.

DATES: Effective January 30, 2007.

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 1997, FDA asked that REDUX (dexfenfluramine HCl) be withdrawn from the market because of safety concerns; Indevus (formerly Interneuron Pharmaceuticals, Inc.) discontinued marketing this product. REDUX (dexfenfluramine HCl)Capsules, a treatment for obesity, was withdrawn from the market after review of safety data showed that the product is associated with valvular heart disease (see FDA press releases on ''Health Advisory on Fenfluramine/Phentermine for Obesity,'' dated July 8, 1997, (*http://www.fda.gov/opacom/hpnews.html*), and ''FDA Announces Withdrawal of Fenfluramine and Dexfenfluramine,'' dated September 15, 1997, (*http://www.fda.gov/opacom/hpnews.html*)).

In a letter dated January 16, 2006, Indevus requested that FDA withdraw approval, under § 314.150(d) (21 CFR 314.150(d)), of NDA 20–344 for REDUX (dexfenfluramine HCl) Capsules, stating that it had discontinued marketing the product. The letter also stated that Indevus believes that the risk/benefit ratio for the use of dexfenfluramine is unfavorable and that withdrawal of approval of NDA 20–344 is in the best interest of public health. Indevus voluntarily waived its opportunity for a hearing, provided under § 314.150(a) and (b).

Therefore, under section 505(e) of Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)), § 314.150(d), and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs, approval of NDA 20–544, and all amendments and supplements thereto, is withdrawn, effective January 30, 2007. 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. 331(d)).

Dated: January 12, 2007.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E7–1414 Filed 1–29–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be