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

collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Health Education Assistance Loan (HEAL) Program: Physician's Certification of Borrower's Total and Permanent Disability Form (OMB No. 0915–0204): Extension

The Health Education Assistance Loan (HEAL) program provided federally-insured loans to students of allopathic medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, allied health, or chiropractic, and graduate students in health administration or clinical psychology through September 30, 1998. Eligible lenders, such as banks, savings and loan associations, credit unions, pension funds, State agencies, HEAL schools, and insurance companies, make new refinanced HEAL loans which are insured by the Federal Government against loss due to borrower's death, disability, bankruptcy, and default. The basic purpose of the program was to assure the availability of funds for loans to eligible students who needed to borrow money to pay for their educational loans. Currently, the program monitors the federal liability, and assists in default prevention activities.

The HEAL borrower, the borrower's physician, and the holder of the loan complete the Physician's Certification form to certify that the HEAL borrower meets the total and permanent disability provisions. The Department uses this form to obtain detailed information about disability claims which includes the following: (1) The borrower's consent to release medical records to the Department of Health and Human Services and to the holder of the borrower's HEAL loans; (2) pertinent information supplied by the certifying physician; (3) the physician's certification that the borrower is unable to engage in any substantial gainful activity because of a medically determinable impairment that is expected to continue for a long and indefinite period of time or to result in death; and, (4) information from the lender on the unpaid balance. Failure to submit the required documentation will result in disapproval of a disability claim. No changes have been made to the current form.

The estimate of burden for the Physician's Certification form is as follows:

Respondent	Number of respondents	Responses per respondent	Total responses	Hours per response (minutes)	Total burden hours
Borrower	80	1	80	5	7
Physician	80	1	80	30	40
Loan Holder	17	5	85	10	14
Total	177	.....	425	.....	61

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 24, 2007.

Caroline Lewis,

Acting Associate Administrator for Administration and Financial Management.

[FR Doc. E7–1437 Filed 1–29–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: HRSA AIDS Education and Training Centers Evaluation Activities (OMB No. 0915–0281)—Revision

The AIDS Education and Training Centers (AETC) Program, under the Ryan White HIV/AIDS Treatment Modernization Act of 2006, supports a network of regional and cross-cutting national centers that conduct targeted, multi-disciplinary education and training programs for health care providers treating persons with HIV/AIDS. The purpose of the AETCs is to increase the number of health care providers who are effectively educated and motivated to counsel, diagnose, treat, and medically manage individuals with HIV infection, and to help prevent high risk behaviors that lead to HIV transmission.

As part of an ongoing evaluation effort of AETC activities, information is needed on AETC training sessions, consultations, and technical assistance activities. Each regional center collects forms on AETC training events, and centers are required to report aggregate data on their activities to HRSA and the HIV/AIDS Bureau (HAB). This data collection provides information on the number of training events, including clinical trainings and consultations, as well as technical assistance activities conducted by each regional center, the number of health care providers receiving professional training or consultation, and the time and effort expended on different levels of training and consultation activities. In addition, information is obtained on the populations served by the AETC trainees, and the increase in capacity achieved through training events. Collection of this information allows HRSA/HAB to provide information on training activities, types of education, and training provided to Ryan White CARE Act grantees, resource allocation, and capacity expansion.

Trainees are asked to complete the Participant Information Form (PIF) for each activity they complete, and trainers are asked to complete the Event Record (ER). The estimated annual response burden to the attendees of training programs is as follows: