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]

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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