forged, with the intent to create a false impression of a state of facts. Dr. Hendrick was paid by GlaxoSmithKline approximately $116,800 in X-ray fees for his participation in the clinical research trial. In so doing he caused a check to be mailed to him through the Postal Service at the direction of GlaxoSmithKline as partial payment for his participation in the clinical trial for the purpose of executing the scheme to defraud.

As a result of this conviction, FDA sent Dr. Hendrick by certified mail on May 4, 2009, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) and (a)(2)(B) of the act, that Dr. Hendrick was convicted of a felony under Federal law for conduct relating to the development or approval of a drug product, including the process for development or approval of a drug product, and conduct otherwise relating to the regulation of a drug product under the act. The proposal also offered Dr. Hendrick an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Hendrick did not request a hearing and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(A) and (a)(2)(B) of the act, and under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Dr. Hendrick has been convicted of a felony under Federal law for conduct relating to the development or approval of a drug product, including the process for development or approval, of a drug product, and conduct otherwise relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Dr. Hendrick 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**) (see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii), and 321(dd)). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Dr. Hendrick, in any capacity, during Dr. Hendrick's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Dr. Hendrick, 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 Dr. Hendrick during his permanent debarment (section 306(c)(1)(B) of the act).

Any application by Dr. Hendrick for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA–2008–N–0582 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: July 15, 2009.

Alyson L. Saben,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. E9–18621 Filed 8–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0501]

Paul H. Kornak: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Paul H. Kornak 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 Paul H. Kornak was convicted of three felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product, and for conduct otherwise relating to the regulation of a drug product under the act. After being given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, Mr. Kornak failed to request a hearing. Mr. Kornak's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 4, 2009.

ADDRESSES: Submit applications for special 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: Robert L. Hummel, Sr., Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6845.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Section 306(a)(2)(B) of the act requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of any drug product under the act.

On January 18, 2005, the U.S. District Court for the Northern District of New York accepted Mr. Kornak's plea of guilty and entered judgment against Mr. Kornak for one count of making and using a materially false statement, one count of mail fraud, and one count of criminally negligent homicide, federal felony offenses under 18 U.S.C. 1001(a)(3), 1341 and 1346, and 13, respectively. The actions underlying these convictions were committed while Mr. Kornak was employed by the Department of Veterans Affairs as the coordinator of several clinical studies of drug products. Mr. Kornak participated in a scheme to defraud the sponsors of these studies by repeatedly submitting false documentation and enrolling and causing to be enrolled persons as study subjects who did not qualify under particular study protocols. Mr. Kornak admitted to submitting a case report form with regard to a study subject knowing the document contained

materially false laboratory entries and altered information from a radiology display report, which were critical factors in determining whether the individual was eligible to participate in the clinical study. He also admitted to knowingly and willfully misrepresenting the results of a blood chemistry analysis related to the participation of a study subject who would not otherwise have met the criteria for that study. The subject was administered chemotherapeutic drugs in connection with the clinical study and died as a result thereof. Mr. Kornak's failure to perceive a substantial and unjustifiable risk that death would occur when he knowingly and willingly made and used such false documents constituted a gross deviation from the standard of care that a reasonable person would observe in the situation. Mr. Kornak further admitted to knowingly and willfully using interstate mail for the purpose of executing the aforesaid scheme and artifice to defraud, deprive, and obtain money and property.

As a result of these convictions, FDA sent Mr. Kornak by certified mail on May 4, 2009, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) and (a)(2)(B) of the act, that Mr. Kornak was convicted of felonies under Federal law for conduct relating to the development or approval of a drug product, and for conduct otherwise relating to the regulation of a drug product under the act. The proposal also offered Mr. Kornak an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Kornak did not request a hearing and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(A) and (a)(2)(B) of the act, and under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Mr. Kornak has been convicted of felonies under Federal law for conduct relating to the development of approval of a drug product and conduct otherwise relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Mr. Kornak 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**) (see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii), and 321(dd)). Any person with an approved or pending drug product application who knowingly employs or retains Mr. Kornak as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Kornak during Mr. Kornak's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Kornak, 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. Kornak during his period of debarment (section 306(c)(1)(B) of the act).

Any application by Mr. Kornak for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 2007–N–0501 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: July 20, 2009.

Alyson L. Saben,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. E9–18619 Filed 8–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–E–0258; FDA–2008–E–0260; and FDA–2008–E–0261]

Determination of Regulatory Review Period for Purposes of Patent Extension; RECOTHROM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for RECOTHROM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of three applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human biological product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the human biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the human biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include