faculty at the DISL are actively involved in both basic and applied research in coastal waters of the northern Gulf of Mexico. The DISL operates marine research vessels (boats) crewed by faculty and students for field studies and sample collections. DISL possesses extensive laboratory and wet-laboratory resources relevant to the mission of the FDA/GCSL. The DISL is located within 1 mile of the FDA/GCSL which will engage the proposed program of collaboration and internships. This unique circumstance of capability, capacity and proximity is irreplaceable without extended and costly concessions.

II. Award Information/Funds Available

A. Award Amount

The estimated amount of support in FY09 will be up to $250,000 total costs (direct plus indirect costs).

B. Length of Support

The award will provide 12 months of support contingent upon satisfactory performance in the achievement of project and program reporting.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *http://www.cfsan.fda.gov/list.html*. Persons interested in applying for a grant may obtain an application from the PHS 398 application instructions available at *http://grants.nih.gov/grants/forms.htm*. The following steps are required for paper submission:

- Step 1: Obtain a Dun and Bradstreet Number (DUNS)

Applicants are now required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number that uniquely identifies business entities. To obtain a DUNS number, call DUN and Bradstreet at 1–866–705–5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet. For foreign entities the Web site *https://eupdate.DNB.com*.

- Step 2: Register With Central Contractor Registration (CCR)

Applicants must register with the CCR database. You must have a DUNS number to begin your registration. This database is a government-wide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. The preferred method for completing a registration is through the Web site at *https://www.ccr.gov*. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online pre-registration, as well as steps to walk you through the registration process.

- Step 3: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp*. Step 3, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp*. After you have followed these steps, submit paper applications to: Camille Peake, Division of Acquisition Support and Grants, Food and Drug Administration (HFA 500), 5630 Fishers Lane, rm. 2139, Rockville, MD 20857, 301–827–7175, FAX: 301–827–7101, e-mail: *Camille.Peake@fda.hhs.gov*.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–18533Filed 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–N–0582]

Kim C. Hendrick: 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 Kim C. Hendrick, M.D., from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Dr. Hendrick was convicted of a felony 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, Dr. Hendrick failed to request a hearing. Dr. Hendrick'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 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 September 11, 2007, the U.S. District Court for the Eastern District of Michigan accepted Dr. Hendrick's guilty plea and entered judgment against him for one count of mail fraud, a federal felony offense under 18 U.S.C. 1341. This offense was committed when Dr. Hendrick was a licensed physician practicing medicine in the State of Michigan. Dr. Hendrick agreed to participate in the clinical research trial for Augmentin XR, including its use in the treatment of adults with Acute Bacterial Sinusitis (ABS). As part of his participation in the clinical study, he agreed to conduct the study in conformity with the protocol established by GlaxoSmithKline and to comply with FDA regulations. He also agreed to take X-rays, before and after treatment, of persons he diagnosed with ABS, and to have an independent radiologist analyze these and issue reports regarding the X-rays.

Dr. Hendrick admitted that instead of having an independent radiologist review the X-rays and issue reports, he allowed certain X-rays to be sent in batch form, which was a direct violation of the protocol. Further, he did not verify the purported signatures of the independent radiologist reports and, instead, failed to disclose to GlaxoSmithKline and/or FDA that the signatures were unverified and possibly

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