Dated: December 13, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31693 Filed 12–16–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0235]

Ehigiator O. Akhigbe: 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 FD&C Act) debarring Ehigiator O. Akhigbe, MD for 25 years 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. Akhigbe was convicted of 17 felonies for conduct involving fraud, false statement and falsification or destruction of records. Dr. Akhigbe was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Akhigbe failed to respond. Dr. Akhigbe's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This Order is effective December 17, 2010.

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: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6844.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a felony which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, and it finds, on the basis of the conviction and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that individual may violate requirements under the Act relating to drug products.

On March 19, 2010, the United States District Court for the District of Columbia entered judgment against Dr. Akhigbe for one count of health care fraud in violation of 18 U.S.C. 1347, and 16 counts of false statements in health care matters in violation of 18 U.S.C. 1035.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for those convictions is as follows: Dr. Akhigbe was a medical doctor with licenses to practice in the District of Columbia, Maryland, Pennsylvania, and Virginia. The District of Columbia Medicaid Program contracted with Amerigroup Corp. (Amerigroup) to act as its fiscal agent for the processing and payment of claims submitted by Medicaid providers. On or about December 6, 2001, Dr. Akhigbe entered into a Participating Physician Agreement with Amerigroup whereby he agreed to provide healthcare services to District of Columbia Medicaid beneficiaries.

Dr. Akhigbe prepared and submitted his own billing to Amerigroup for medical services he purportedly provided to his patients. For each billed visit, Dr. Akhigbe or others acting at his direction, generated insurance claim forms which included his certification that all of the information on the claim forms was accurate. From on or about December 6, 2001, until the termination of his contract with Amerigroup on June 24, 2004, Dr. Akhigbe submitted approximately 3,957 claims to Amerigroup for services he purportedly provided to Medicaid patients and sought approximately $807,347.00 from Amerigroup.

Beginning in approximately December 2002, and continuing to approximately May 2005, in the District of Columbia and elsewhere, Dr. Akhigbe knowingly, willfully, and with intent to defraud, executed a scheme and artifice to defraud Amerigroup as to material matters in connection with the delivery of any payment for health care benefits, items, and services, and to obtain money from Amerigroup by means of material false and fraudulent pretenses and representations and the concealment of material facts in connection with the delivery of and payment for health care benefits, items, and services. As part of his scheme, Dr. Akhigbe repeatedly prepared and submitted false claims in which he purported to have performed surgical or invasive medical procedures on District of Columbia Medicaid patients that were never performed, he billed for office visits that never occurred, and he continued to bill for a period of time after a minor or major procedure during which no additional bills could be submitted. In order to conceal from Amerigroup that he was billing for procedures that he had not performed, Dr. Akhigbe created false progress notes indicating the dates, times and medical procedures that he claimed to have performed and inserted the false progress notes into his patients' medical files to corroborate a number of false claims.

As a result of his convictions, on September 13, 2010, FDA sent Dr. Akhigbe a notice by certified mail proposing to debar him for 25 years 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(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)), that Dr. Akhigbe was convicted of felonies for conduct involving fraud, false statement and falsification or destruction of records and that Dr. Akhigbe has demonstrated a pattern of conduct sufficient to find that there is reason to believe that individual may violate requirements under the FD&C Act relating to drug products. The proposal also offered Dr. Akhigbe 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. Akhigbe failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under Section 306(b)(2)(B)(ii)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(ii)(I)) under authority delegated to him (Staff Manual Guide 1410.35), finds that Ehigiator O. Akhigbe has been convicted of felonies for conduct involving fraud, false statement and falsification or destruction of records.

As a result of the foregoing finding, Dr. Akhigbe is debarred for 25 years 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 FD&C 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 section 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(iii), 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. Akhigbe, in any capacity during Dr. Akhigbe's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Dr. Akhigbe provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Akhigbe during his period of debarment (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B)).

Any application by Dr. Akhigbe for termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2010–N–0235 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: November 19, 2010.

Howard R. Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2010–31776 Filed 12–16–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: January 19, 2011, 8:30 a.m.–4 p.m., January 20, 2011, 8:30 a.m.–12:15 p.m.

Place: Hilton Washington DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852. Telephone: (301) 468–1100.

Status: The meeting will be open to the public.

Agenda: On the morning of January 19, following welcoming remarks from the COGME Chair, HRSA senior management, and the Executive Secretary of COGME, there will be an introduction of COGME members.

The rest of the first day will consist of presentations covering various aspects of graduate medical education, Bureau of Health Professions activities concerning health workforce issues, a study of primary care physician projections by state, and work of the Medicare Payment and Advisory Commission on GME issues.

On January 20, there will be presentations on the findings and recommendations of COGME's 20th report, *Advancing Primary Care* (cover date December 2010). It is expected that the rest of the morning will be taken up in discussions in exploring the topic for COGME's next report.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerald M. Katzoff, Executive Secretary, COGME, Division of Medicine and Dentistry, Bureau of Health Professions, Parklawn Building, Room 9A–27, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–4443. The Web address for information on the Council and the January 19–20, 2011 meeting agenda is *http://cogme.gov.*

Dated: December 9, 2010.

Robert Hendricks,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–31712 Filed 12–16–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors: Improving the Safety of the U.S. Blood Supply Through Hemovigilance

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 28, 2010, Volume 75, No. 187, pages 59724–59725 and allowed 60 days for public comment. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a current valid OMB control number.

Proposed Collection: Title: Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the U.S. blood supply through hemovigilance. Type of Information Collection Request: NEW. Need and Use of Information Collection: Information on current risk factors in blood donors as assessed using analytical study designs is largely unavailable in the U.S. Studies of risk factor profiles among HIV-infected donors were funded by the CDC for approximately 10 years after implementation of serologic screening in the mid-1980s, whereas studies of HTLV- and HCV-seropositive (and indeterminate) donors, funded by NIH, were conducted in the early 1990s, but unfortunately, none of these studies is ongoing. Infection trend analyses have been conducted by the American Red Cross (ARC). The findings show continued HIV risk with the prevalence of HIV in first time donors hovering around 10 per 100,000 donations in each of the last 10 years and the incidence in repeat donors increasing from 1.49 per 100,000 person-years in 1999–2000 to 2.16 per 100,000 persons-years in 2007–2008. While the prevalence of HCV in first time donors decreased over this time interval from 345 to 163 per 100,000 donations, the incidence in repeat donors did not decrease and evidence of incident infection in first time donors increased. Moreover specific age, gender and race/ethnicity groups were over-represented. Significantly increased incidence of both HIV and HCV were observed in 2007/2008 compared to 2005/2006. Similar analyses for HBV have shown an incidence in all donors of 3.4 per 100,000 person-years which is lower