and acceptability of its services, developments in the health status of its enrollees, and other matters that CMS may require. Data collected via Medicare Part C Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the benefits provided by MA plans to enrollees. *Form Number:* CMS–10261 (OMB# 0938–1054); *Frequency:* Yearly, Quarterly; Affected *Public:* Business or other for-profits; *Number of Respondents:* 588; *Total Annual Responses:* 1158; *Total Annual Hours:* 245,528. (For policy questions regarding this collection contact Terry Leid at 410–786–8973. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements and Supporting Regulations; *Use:* 42 CFR part 423, § 423.514, requires each Part D Sponsor to have an effective procedure to provide statistics indicating: the cost of its operations, the patterns of utilization of its services, the availability, accessibility, and acceptability of its services, information demonstrating it has a fiscally sound operation and other matters as required by CMS. In addition, subsection 423.505 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), establishes as a contract provision that Part D Sponsors must comply with the reporting requirements for submitting drug claims and related information to CMS. Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit Group. *Form Number:* CMS–10185 (OMB#: 0938–0992); *Frequency:* Yearly, Quarterly, Semi-Annually; *Affected Public:* Private sector, business or other for-profit; *Number of Respondents:* 2993; Total *Annual Responses:* 48,490; *Total Annual Hours:* 128,754. (For policy questions regarding this collection contact LaToyia Grant at 410–786–5434. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Collection of Encounter Data from Medicare Advantage Organizations; *Use:* The Centers for Medicare and Medicaid Services (CMS) intends to collect encounter data, or data on each item or service delivered to an enrollee, from Medicare Advantage Organizations. Medicare Advantage organizations will obtain this data from providers. CMS would collect the data electronically from Medicare Advantage Organizations via the Health Insurance Portability and Accountability Act (HIPAA) compliant standard Health Care Claims transactions for professional data and institutional data. The information is used to submit health care claims or equivalent health encounter information, carry out health plan enrollments and disenrollments, determine health plan eligibility, send and receive health care payment and remittance advices, transmit health plan premium payments, determine health care claim status, provide referral certifications and authorizations, and coordinate the benefits for individuals who have more than one health plan. *Form Number:* CMS–10340 (OMB#: 0938–New); *Frequency:* Weekly; *Affected Public:* Private sector; businesses or other for-profits; *Number of Respondents:* 678; Total *Annual Responses:* 384,041,063; *Total Annual Hours:* 768. (For policy questions regarding this collection contact Sean Creighton at 410–786–9302 or Deondra Moseley at 410–786–4577. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *February 15, 2011:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: December 10, 2010.

Martique Jones,

Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–31541 Filed 12–16–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0627]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Food and Drug Administration Approval to Market a New Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements governing applications for FDA approval to market a new drug.

DATES: Submit either electronic or written comments on the collection of information by February 15, 2011.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal

Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Application for FDA Approval to Market a New Drug—(OMB Control Number 0910–0001)—Extension

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or 505(j) of the FD&C Act is effective with respect to such a drug. Under the FD&C Act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination whether the product is safe and effective for use.

This information collection approval request is for all information requirements imposed by the regulations under part 314 (21 CFR 314) on sponsors who apply for approval of a new drug application (NDA) or abbreviated new drug application (ANDA) in order to market or to continue to market a drug.

Section 314.50(a) requires that the applicant submit an application form (Form FDA 356h) that includes introductory information about the drug as well as a checklist of enclosures.

Section 314.50(b) requires that the applicant submit an index with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that the applicant submit a summary of the application that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; statistical; and pediatric use sections.

Section 314.50(e) requires that the applicant submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that the applicant submit case report forms and tabulations with the archival copy.

Section 314.50(h) requires that the applicant submit patent information, as described under § 314.53, with the application. (The burden hours for § 314.50(h) are already approved by OMB under OMB control number 0910–0513 and are not included in the burden estimates in table 1 of this document.)

Section 314.50(i) requires that the applicant submit patent certification information in section 505(b)(2) applications for patents claiming the drug, drug product, or method of use.

Section 314.50(j) requires that applicants that request a period of marketing exclusivity submit certain information with the application.

Section 314.50(l) requires that the applicant submit an archival, review, and field copy of the application.

Section 314.52 requires that a section 505(b)(2) applicant that relies on a listed drug send any notice of certification of invalidity or noninfringement of a patent to each patent owner and the NDA holder . At the time notice is provided, a 505(b)(2) applicant is required to amend its application to include a statement certifying that the required notice has been provided. A section 505(b)(2) applicant also is required to amend its application to document receipt of the required notice.

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the FD&C Act. (The information collection burden estimate for section 505(b)(2) applications is included in table 1 of this document under the estimates for § 314.50(a), (b), (c), (d), (e), (f), and (k)).

Section 314.60 sets forth reporting requirements for sponsors who amend an unapproved application.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that applicants submit supplements to FDA for certain changes to an approved application.

Section 314.72 requires that sponsors report to FDA any transfer of ownership of an application.

Section 314.80(c)(1) and (c)(2) sets forth requirements for expedited adverse drug experience postmarketing reports and followup reports, as well as for periodic adverse drug experience postmarketing reports (Form FDA 3500A). (The burden hours for § 314.80(c)(1) and (c)(2) are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the burden estimates in table 1 of this document.)

Section 314.80(i) establishes recordkeeping requirements for reports of postmarketing adverse drug experiences. (The burden hours for § 314.80(i) are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the burden estimates in table 1 of this document.)

Section 314.81(b)(1) requires that applicants submit field alert reports to FDA (Form FDA 3331).

Section 314.81(b)(2) requires that applicants submit annual reports to FDA (Form FDA 2252).

Section 314.81(b)(3)(i) requires that applicants submit drug advertisements and promotional labeling to FDA (Form FDA 2253).

Section 314.81(b)(3)(iii) sets forth reporting requirements for sponsors who withdraw an approved drug product from sale. (The burden hours for § 314.81(b)(3)(iii) are already approved by OMB under OMB control number 0910–0045 and are not included in the burden estimates in table 1 of this document.)

Section 314.90 sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.50 through 314.81. (The information collection burden estimate for NDA waiver requests is included in table 1 of this document under estimates for §§ 314.50, 314.60, 314.70, and 314.71.)

Section 314.93 sets forth requirements for submitting a suitability petition in accordance with 21 CFR 10.20 and 10.30. (The burden hours for § 314.93 are already approved by OMB under OMB control number 0910–0183 and are not included in the burden estimates in table 1 of this document.)

Section 314.94(a) and (d) requires that an ANDA contain the following information: Application form; table of contents; basis for ANDA submission; conditions of use; active ingredients; route of administration, dosage form, and strength; bioequivalence; labeling; chemistry, manufacturing, and controls; samples; patent certification.

Section 314.95 requires that ANDA applicants send any notice of certification of invalidity or noninfringement of a patent to each patent owner and the NDA holder.

Section 314.96 sets forth requirements for amendments to an unapproved ANDA.

Section 314.97 sets forth requirements for submitting supplements to an approved ANDA for changes that require FDA approval.

Section 314.98(a) sets forth postmarketing adverse drug experience reporting and recordkeeping requirements for ANDAs. (The burden hours for § 314.98(a) are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the burden estimates in table 1 of this document.)

Section 314.98(c) requires other postmarketing reports for ANDAs: Field alert reports (Form FDA 3331), annual reports (Form FDA 2252), and advertisements and promotional labeling (Form FDA 2253). (The information collection burden estimate for field alert reports is included in table 1 of this document under § 314.81(b)(1); the estimate for annual reports is included under § 314.81(b)(2); the estimate for advertisements and promotional labeling is included under § 314.81(b)(3)(i).)

Section 314.99(a) requires that sponsors comply with certain reporting requirements for withdrawing an unapproved ANDA and for a change in ownership of an ANDA.

Section 314.99(b) sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.92 through 314.99. (The information collection burden estimate for ANDA waiver requests is included in table 1 of this document under estimates for § 314.94(a) and (d) and §§ 314.96 and 314.97.)

Section 314.101(a) states that if FDA refuses to file an application, the applicant may request an informal conference with FDA and request that the application be filed over protest.

Section 314.107(c) requires that the first applicant who submits a substantially complete ANDA containing a certification that a relevant patent is invalid, unenforceable, or will not be infringed submit notice to FDA of the date of first commercial marketing of its drug product.

Section 314.107(e) requires that an applicant submit a copy of the entry of the order or judgment to FDA within 10 working days of a final judgment.

Section 314.107(f) requires that ANDA or section 505(b)(2) applicants notify FDA immediately of the filing of any legal action filed within 45 days of receipt of the notice of certification. A patent owner may also notify FDA of the filing of any legal action for patent infringement. If the patent owner or approved application holder who is an exclusive patent licensee waives its opportunity to file a legal action for patent infringement within the 45-day period, the patent owner or approved application holder must submit to FDA a waiver in the specified format.

Section 314.110(b)(3) states that, after receipt of an FDA complete response letter, an applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (The burden hours for § 314.110(b)(3) are included under parts 10 through 16 (21 CFR parts 10 and 16) hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.110(c) states that, after receipt of a complete response letter, an applicant may notify FDA that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.122(a) requires that an ANDA or a suitability petition that relies on a listed drug that has been voluntarily withdrawn from sale must be accompanied by a petition seeking a determination whether the drug was withdrawn for safety or effectiveness reasons. (The burden hours for § 314.122(a) are already approved by OMB under OMB control number 0910–0183 and are not included in the burden estimates in table 1 of this document.)

Section 314.122(d) sets forth requirements for relisting petitions for unlisted discontinued products. (The burden hours for § 314.122(d) are already approved by OMB under OMB control number 0910–0183 and are not included in the burden estimates in table 1 of this document.)

Section 314.126(c) sets forth requirements for a petition to waive criteria for adequate and well-controlled studies. (The burden hours for § 314.126(c) are already approved by OMB under OMB control number 0910–0183 and are not included in the burden estimates in table 1 of this document.)

Section 314.151(a) and (b) sets forth requirements for the withdrawal of approval of an ANDA and the applicant's opportunity for a hearing and submission of comments. (The burden hours for § 314.151(a) and (b) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.151(c) sets forth the requirements for withdrawal of approval of an ANDA and the applicant's opportunity to submit written objections and participate in a limited oral hearing. (The burden hours for § 314.151(c) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.153(b) sets forth the requirements for suspension of an ANDA when the listed drug is voluntarily withdrawn for safety and effectiveness reasons, and the applicant's opportunity to present comments and participate in a limited oral hearing. (The burden hours for § 314.152(b) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.161(b) and (e) sets forth the requirements for submitting a petition to determine whether a listed drug was voluntarily withdrawn from sale for safety or effectiveness reasons. (The burden hours for § 314.161(b) and (e) are already approved by OMB under OMB control number 0910–0183 and are not included in the burden estimates in table 1 of this document.)

Section 314.200(c), (d), and (e) requires that applicants or others subject to a notice of opportunity for a hearing who wish to participate in a hearing file a written notice of participation and request for a hearing as well as the studies and data on which they relied. Other interested persons may also submit comments on the notice. The section also sets forth the content and format requirements for the applicants' submission in response to notice of opportunity for hearing. (The burden hours for § 314.200(c), (d), and (e) are included under parts 10 through 16 hearing regulations, in accordance with

§ 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.200(f) states that participants in a hearing may make a motion to the presiding officer for the inclusion of certain issues in the hearing. (The burden hours for § 314.200(f) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.200(g) states that a person who responds to a proposed order from FDA denying a request for a hearing provide sufficient data, information, and analysis to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing. (The burden hours for § 314.200(g) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.420 states that an applicant may submit to FDA a drug master file in support of an application, in accordance with certain content and format requirements.

Section 314.430 states that data and information in an application are disclosable under certain conditions, unless the applicant shows that extraordinary circumstances exist. (The burden hours for § 314.430 are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.530(c) and (e) states that if FDA withdraws approval of a drug approved under the accelerated approval procedures, the applicant has the opportunity to request a hearing and submit data and information. (The burden hours for § 314.530(c) and (e) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and are not included in the burden estimates in table 1 of this document.)

Section 314.530(f) requires that an applicant first submit a petition for stay of action before requesting an order from a court for a stay of action pending review. (The burden hours for § 314.530(f) are already approved by OMB under OMB control number 0910–0194 and are not included in the burden estimates in table 1 of this document.)

Section 314.610(b)(1) requires that applicants include a plan or approach to postmarketing study commitments in applications for approval of new drugs when human efficacy studies are not ethical or feasible, and that applicants provide status reports of postmarketing study commitments. (The information collection burden estimate for § 314.610(b)(1) is included in table 1 of this document under the estimates for §§ 314.50 (a), (b), (c), (d), (e), (f), and (k) and 314.81(b)(2)).

Section 314.610(b)(3) requires that in applications for approval of new drugs when human efficacy studies are not ethical or feasible applicants propose labeling to provide to patient recipients. (The information collection burden estimate for § 314.610(b)(3) is included in table 1 of this document under the estimates for § 314.50(e)).

Section 314.630 requires that applicants provide postmarketing safety reporting for applications for approval of new drugs when human efficacy studies are not ethical or feasible. (The burden hours for § 314.630 are already approved by OMB under OMB control numbers 0910–0230 and 0910–0291 and are not included in the burden estimates in table 1 of this document.)

Section 314.640 requires that applicants provide promotional materials for applications for approval of new drugs when human efficacy studies are not ethical or feasible. (The information collection burden estimate for § 314.640 is included in table 1 of this document under the estimates for § 314.81(b)(3)(i)).

Respondents to this collection of information are all persons who submit an application or abbreviated application or an amendment or supplement to FDA under part 314 to obtain approval of a new drug, and any person who owns an approved application or abbreviated application.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section; [Form Number]	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
314.50 (a), (b), (c), (d), (e), (f), and (k)	92	1.36	126	1,917	241,542
314.50(i) and 314.94(a)(12)	96	9.61	923	2	1,846
314.50(j)	71	4.02	286	2	572
314.52 and 314.95	71	3.66	260	16	4,160
314.60	349	21.67	7,564	80	605,120
314.65	10	1.20	12	2	24
314.70 and 314.71	620	4.91	3,050	150	457,500
314.72	104	2.98	310	2	620
314.81(b)(1) [3331]	147	2.57	378	8	3,024
314.81(b)(2) [2252]	656	13.84	9,084	40	363,360
314.81(b)(3)(i) [2253]	490	61.48	30,130	2	60,260
314.94(a)(1)–(11) and (d)	110	7.83	862	480	413,760
314.96	292	35.82	10,461	80	836,880
314.97	197	26.23	5,169	80	413,520
314.99(a)	53	2.30	122	2	244
314.101(a)	1	1	1	.50	.50
314.107(c)—	56	4.1	230	.50	115
314.107(e)—	25	3.92	98	.50	49
314.107(f)—	56	4.1	230	.50	115
314.110(c)	11	1.36	15	.50	7.5
314.420	524	1.98	1,038	61	63,318
Total					3,466,037

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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