

Dated: November 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1106]

Armando Santos: 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 Armando Santos from providing services in any capacity to a person that has an approved or pending drug product application for a period of 12 years. FDA bases this order on a finding that Mr. Santos was convicted of seven felony counts under Federal law for conduct involving health care fraud, conspiracy to commit health care fraud, and false statements related to health care matters and that this pattern of conduct is sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. Mr. Santos was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Santos failed to respond. Mr. Santos's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective November 10, 2014.

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, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rm. 4144, Rockville, MD 20857, 301-796-4640.

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 debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law

for conduct that 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 the individual may violate requirements under the FD&C Act relating to drug products.

On August 15, 2011, the U.S. District Court for the Southern District of Florida entered judgment against Mr. Santos after a jury found him guilty of four counts of health care fraud in violation of 18 U.S.C. 1347, one count of conspiracy to commit health care fraud in violation of 18 U.S.C. 1349, and two counts of false statements related to health care matters in violation of 18 U.S.C. 1035(a)(2).

The FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: Mr. Santos was a registered nurse working for a home health agency located in the Southern District of Florida. As a registered nurse in the home health field, it was Mr. Santos's duty to provide skilled nursing services to patients and maintain proper documentation of all treatments provided to patients.

From on or about June 29, 2007, through on or about March 13, 2009, Mr. Santos conspired with others to defraud Medicare. Mr. Santos and his co-conspirators, among other things, submitted and caused the submission of false and fraudulent claims to Medicare, and paid kickbacks and bribes to Medicare beneficiaries in exchange for the use of their Medicare beneficiary numbers as the bases of claims filed for home health care. Mr. Santos and his co-conspirators signed patient assessment forms falsely certifying that Medicare beneficiaries were in need of home health services that were medically unnecessary.

Mr. Santos created false weekly visit/time records in which he claimed to be providing skilled nursing services to two separate Medicare beneficiaries at the same time. On four separate occasions, Mr. Santos submitted and caused the submission of false and fraudulent claims to Medicare, representing that he had provided various home health services to beneficiaries pursuant to physicians' plans of care. He caused a home health agency to submit approximately \$230,315 in false and fraudulent claims

to Medicare for home health services allegedly rendered to Medicare beneficiaries, when such home health services were not medically necessary and had not been provided. As a result of these fraudulent claims, Mr. Santos caused Medicare to make payments of approximately \$152,664 to a Miami-Dade County home health agency.

In addition, Mr. Santos knowingly and willfully made materially false statements and representations, in connection with the delivery of and payment for health care benefits, items, and services. Specifically, Mr. Santos prepared documents entitled "Skilled Nursing Progress Note[s]" which falsely stated that he had injected Medicare beneficiaries with insulin on two occasions, when he knew he had not performed these services.

As a result of his convictions, on April 9, 2014, FDA sent Mr. Santos a notice by certified mail proposing to debar him for 12 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on the finding, under section 306(b)(2)(B)(ii)(I) of the FD&C Act, that Mr. Santos was convicted of seven felonies under Federal law for conduct involving health care fraud, conspiracy to commit health care fraud, and false statements related to health care matters, and that the Agency found, on the basis of these convictions and other information, that Mr. Santos had demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products. This conclusion was based on the fact that Mr. Santos had legal and professional obligations to ensure that he kept accurate medical records for each patient and that he submitted accurate medical claims for services he provided. Instead, Mr. Santos signed patient assessment forms falsely certifying that Medicare beneficiaries were in need of home health services that were medically unnecessary, and he submitted false weekly visit/time records. Mr. Santos additionally prepared false "Skilled Nursing Progress Note[s]" stating that he had injected two Medicare beneficiaries with insulin when he had not done so. He submitted and caused the submission of false and fraudulent claims to Medicare. He engaged in this conduct repeatedly over a period of almost 2 years. His convictions indicate that he knowingly and willfully disregarded his legal and professional obligations to keep accurate medical records and to submit accurate claims for the services he provided.

Having considered the conduct that forms the basis of his conviction and the fact that this conduct occurred in the course of his profession and showed a disregard for the obligations of his profession, FDA finds that Mr. Santos has demonstrated a pattern of conduct sufficient to find that there is reason to believe that, if he were to provide services to a person that has an approved or pending drug application, he may violate requirements under the FD&C Act relating to drug products. Therefore, FDA has reason to believe that, if Mr. Santos were to provide services to a person that has an approved or pending drug application, he may violate requirements under the FD&C Act relating to drug products.

The proposal offered Mr. Santos 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. The proposal was received on April 16, 2014. Mr. Santos failed to respond within the timeframe prescribed by regulation 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 Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, under section 306(b)(2)(B)(ii)(I) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that Armando Santos has been convicted of seven counts of felonies under Federal law for conduct involving health care fraud, conspiracy to commit health care fraud, and false statements related to health care matters, and, on the basis of these convictions and other information, finds that Mr. Santos has demonstrated a pattern of conduct sufficient to find that there is reason to believe he may violate requirements under the FD&C Act relating to drug products.

As a result of the foregoing finding, Armando Santos is debarred for 12 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 sections 306(c)(1)(B), 306(c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 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 Mr. Santos, in any capacity during his 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 Mr. Santos 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 from Mr. Santos during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Santos for termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2013-N-1106 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.

Any application by Mr. Santos for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2013-N-1106 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 4, 2014.

Armando Zamora,

Deputy Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of an advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committees: Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 18, 2014, from 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: BRUDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The meeting will be closed to permit discussion of whether FDA should permit further clinical development of an existing investigational drug product, which will include the review of trade secret and/or confidential information.

Procedure: On December 18, 2014, from 8:30 a.m. to 9:45 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before December 4, 2014. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:45 a.m. Those individuals interested in making formal