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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0063]

Sami Arshak Yanikian: 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 Sami Arshak Yanikian for 10 years 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 Mr. Yanikian was convicted of two counts of introducing unapproved new drugs into interstate commerce, which relates to the development or approval, including the process for development or approval, of drug products and to the regulation of drug products under the FD&C Act. In addition, the type of conduct that served as the basis for Mr. Yanikian's convictions undermine the process for the regulation of drugs. Mr. Yanikian was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Yanikian failed to respond. Mr. Yanikian's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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,

12420 Parklawn Dr,

Rockville, MD 20857,

301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under the FD&C Act, and if FDA finds that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs.

On June 29, 2011, Mr. Yanikian was found guilty of two counts of introduction of an unapproved drug in interstate commerce, in violation of sections 301(d), 505(a), and 303(a)(1) of the FD&C Act (21 U.S.C. 331(d), 355(a), 333(a)(1)) and of aiding and abetting, in violation of 18 U.S.C. 2(b), and the U.S. District Court for the Central District of California entered judgment against Mr. Yanikian for the misdemeanor offenses of introduction of an unapproved drug in interstate commerce and aiding and abetting.

The FDA's finding that debarment is appropriate is based on the misdemeanor convictions referenced herein. The factual basis for the conviction is as follows: On March 17,

2005, FDA sent Mr. Yanikian a warning letter regarding his marketing and sale of Novel natural formulation for atrial fibrillation, Super Nasal Drops, and Sams No Tinnitus Formulation. The warning letter described the claims Mr. Yanikian's Web site was making pertaining to these products and informed him that his claims caused the products to be "drugs" as defined by the FD&C Act because they were intended to cure, mitigate, treat, or prevent disease. Mr. Yanikian was informed that his products were "new drugs" and that a new drug could not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application was in effect for it. The warning letter additionally noted that none of the products described had an approved application and that their introduction or delivery for introduction into interstate commerce violated section 301(d) of the FD&C Act. Mr. Yanikian was advised to immediately correct the violations.

In response, on April 11, 2005, Mr. Yanikian wrote a reply letter to FDA in which he stated that the products were mailed for sale outside the United States to hospitals that deal with natural health products. He further noted that his products were not intended for sale as over-the-counter or for single individuals in the United States until they were approved by FDA.

Despite knowing that he was not allowed to sell these unapproved new drugs in the United States without FDA approval, and despite his repeated representations to FDA that he was not selling his products to customers in the United States, Mr. Yanikian subsequently sold his unapproved new drug products to an undercover agent in November 2005, and again in November 2006, in violation of sections 301(d), 505(a), and 303(a)(1) of the FD&C Act and 18 U.S.C. 2(b).

As a result of his conviction, on April 3, 2012, FDA sent Mr. Yanikian a notice by certified mail proposing to debar him for 10 years from providing services in any capacity to a

person that has an approved or pending drug product application. FDA subsequently confirmed that Mr. Yanikian personally received the notice on April 11, 2012. The proposal was based on a finding, under section 306(b)(2)(B)(i)(I) of the FD&C Act that Mr. Yanikian was convicted of two counts of a misdemeanor under Federal law. In the notice, FDA found that the conduct underlying these Federal misdemeanor convictions relates to the development or approval, including the process for development or approval, of drug products and relates to the regulation of drug products under the FD&C Act and undermines the process for the regulation of drugs because the introduction and causing the introduction of unapproved new drugs into interstate commerce are prohibited by the FD&C Act. The proposal also offered Mr. Yanikian 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. Yanikian 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)(i)(I) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that Sami Arshak Yanikian has been convicted of two counts of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of drug products and relating to the regulation of drug products under the FD&C Act, and that the type of conduct that served as a basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Mr. Yanikian is debarred for 10 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), (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 Mr. Yanikian, in any capacity during Mr. Yanikian'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 Mr. Yanikian 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 Mr. Yanikian during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Yanikian for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2012-N-0063 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: June 15, 2012.

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

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