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. Shah, in any capacity during Mr. Shah'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. Shah 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 (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Shah during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Shah for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 355a(d)(1)) should be identified with Docket No. FDA–2011–N–0659 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: March 27, 2012.

Armando Zamora,

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

[FR Doc. 2012–8229 Filed 4–4–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0331]

Jose Concepcion: 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 Jose Concepcion for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on findings that Mr. Concepcion was convicted of conspiracy to commit an offense against the United States, that the conduct that served as the basis for the felony conspiracy conviction relates to the development or approval, including the process for development or approval, of any drug product and relates to the regulation of drug products under the FD&C Act, and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. Mr. Concepcion was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Concepcion failed to request a hearing. Mr. Concepcion's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective April 5, 2012.

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., Element Bldg., rm. 4144, Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(II) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits FDA to debar an individual if it finds that the individual has been convicted of a conspiracy to commit a felony 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 a drug product under the FD&C Act, 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 December 1, 2010, based upon a plea of guilty to one count of conspiracy to commit an offense against the United States, in violation of 18 U.S.C. 371, judgment was entered against Mr. Concepcion in the U.S. District Court for the District of New Jersey.

FDA's finding that debarment is appropriate is based on the conspiracy conviction referenced herein. The factual basis for the conviction is as follows: Mr. Concepcion was employed at Able Laboratories, Inc. (Able) from mid-1998 until January 2005. Able developed, manufactured, and sold several generic drug products, including products for cardiac and psychiatric conditions and prescription pain relievers. Mr. Concepcion was employed as a chemist in the Quality Control Department performing analytical tests on Able products to ensure product safety and effectiveness from in or around mid-1998 to around January 2001. In or around January 2001, Mr. Concepcion was promoted to group leader and around April 2002, he was promoted to supervisor in the Quality Control Department.

As group leader and supervisor in the Quality Control Department, Mr. Concepcion's responsibilities included supervising numerous chemists and technicians who performed analytical quality control tests on Able's generic drug products to ensure product safety and effectiveness; monitoring the chemists' compliance with current Good Manufacturing Practices, as required by the FD&C Act and FDA regulations; and ensuring compliance with Able's standard operating procedures (SOPs).

From in or around 1999 through January, 2005, Mr. Concepcion conspired to cause the introduction and delivery for introduction into interstate commerce of a drug that was adulterated and misbranded, with an intent to defraud and mislead, contrary to 18 U.S.C. 371 and 21 U.S.C. 331(a) and 333(a)(2).

Mr. Concepcion and his co-conspirators impaired, impeded, defeated, and obstructed FDA's lawful government function to approve the manufacture and distribution of generic drug products by violating Good Manufacturing Practices; violating SOPs by failing to properly investigate, log, and archive questionable, aberrant, and unacceptable laboratory results so that Able could conceal improprieties and continue to distribute and sell its drug products; manipulating and falsifying testing data and information to conceal from FDA failing laboratory results relating to Able's generic drug products; creating and maintaining false, fraudulent, and inaccurate test results to make it appear that drug products had the requisite identity, strength, quality, and purity characteristics so the drug products could be distributed and sold to increase Able's sales and profit; and creating and maintaining false, fraudulent, and inaccurate data and records to obtain FDA approval to market new product lines.

In furtherance of the conspiracy, in or around December 2001, Mr. Concepcion and his co-conspirators falsified and manipulated testing data relating to stability tests for propoxphene napsylate and acetaminophen.

As a result of his conviction, on January 6, 2012, FDA sent Mr. Concepcion a notice by certified mail proposing to debar him for 5 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)(i)(II) of the FD&C Act, that Mr. Concepcion was convicted of conspiracy to commit an offense against the United States, that the conduct that served as the basis for the felony conspiracy conviction relates to the development or approval, including the process for development or approval, of any drug product and relates to the regulation of drug products under the FD&C Act, and that the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Mr. Concepcion 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. Concepcion failed to request a hearing 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)(II) of the FD&C Act under authority delegated to him (Staff Manual Guide 1410.35), finds that Jose Concepcion has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product 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. Concepcion is debarred for 5 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 Mr. Concepcion, in any capacity during Mr. Concepcion'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. Concepcion 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. Concepcion during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Concepcion for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 355a(d)(1)) should be identified with Docket No. FDA–2009–N–0331 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: March 27, 2012.

Armando Zamora,

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

[FR Doc. 2012–8249 Filed 4–4–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on June 21, 2012, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301–977–8900.

Contact Person: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993–0002, *Avena.Russell@fda.hhs.gov,* 301–796–3805, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On June 21, 2012, the committee will discuss, make recommendations, and vote on information related to the premarket approval application, sponsored by Dune Medical Devices, Inc., for the MarginProbe System, that utilizes electromagnetic waves to characterize human tissue in real time and provides intraoperative information on the malignancy of the surface of the ex vivo lumpectomy specimen.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 11, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before