DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Edward Manookian
(b) (6)

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2015-N-4169

Dear Mr. Manookian:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debarring you from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that you were convicted, as defined in section 306(l)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 335a(l)(1)(B)) of felonies under Federal law[1] for conduct relating to the regulation of a drug product under the Act. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On March 11, 2015, you entered a plea of guilty to two counts of conspiracy to commit an offense against the United States, in violation of 18 U.S.C. §371, and judgment was entered against you in the United States District Court for the Middle District of Tennessee on August 28, 2015. The underlying facts supporting this conviction are as follows.

You were the President and owner of Melanocorp, Inc. (Melanocorp), a for profit corporation that conducted operations in the Middle District of Tennessee, and your duties included overseeing the employees and operations of Melanocorp.

Melanotan II (MII) was a peptide, or series of amino acids, that was marketed, sold, and shipped by Melanocorp to customers in the United States and abroad. Your company advertised MII, an unapproved new drug, as an injectable tanning product through an internet website. The website linked to articles reporting that MII was developed for the purpose of protecting against skin cancer and rosacea. In addition, Melanocorp's website included claims that it could reduce skin cancer claims and cure rosacea. The Melanocorp website also advertised MII as being 100% U.S. made, whereas in fact some of the MII sold by Melanocorp was manufactured in and imported from China.

[1] Under section 306(l)(1)(B) of the Act (21 U.S.C. §335a(l)(1)(B)), for debarment purposes, a person is considered to have been convicted of a criminal offense when a plea of guilty has been accepted by a Federal court.

On or about August 30, 2007, Melanocorp received a warning letter from the FDA expressing concern about Melanocorp's marketing of MII. The warning letter noted that, based on information and statements on the Melanocorp website, MII constituted a new drug under the FDCA that could not be introduced or delivered for introduction into interstate commerce without an FDA approved application. The warning letter concluded that the sale of MII without an FDA approved application violated the FDCA and instructed your company to take prompt action to correct the violations cited in the warning letter. You were aware of the warning letter and its contents.

On or about September 17, 2007, after consulting with counsel, you had a letter sent to FDA stating that Melanocorp had stopped all promotion and sale of MII in the U.S. and had stopped taking orders for MII from U.S. residents. In the letter, you stated that Melanocorp would not accept orders for MII from any individual with a U.S. mailing address and that Melanocorp had stopped taking orders from U.S. residents.

On or about November 29, 2007, the FDA sent a letter to an attorney representing Melanocorp, which reiterated that MII was considered by FDA to be an unapproved drug and warned that its introduction or delivery for introduction into interstate commerce would be a violation of the FDCA. The letter specifically stated that the sale of MII outside the U.S. violated the FDCA. You were aware of this letter and its contents.

On or about December 14, 2007, you had a letter sent to FDA from your attorney confirming that Melanocorp had stopped taking orders for MII from U.S. residents. This letter also stated that Melanocorp did not disagree that FDA considered Melanotan II to be an unapproved new drug and that FDA had requested that Melanocorp not distribute or market the product in the U.S. Your letter also stated Melanocorp's position that it could lawfully export MII, regardless of its status as an unapproved new drug.

On or about December 28, 2007, the FDA sent a letter to your attorney which reiterated that unapproved new drugs do not qualify for export. You were aware of this letter and its contents.

Following receipt of the 2007 correspondence from FDA, Melanocorp continued to ship MII in interstate commerce. Melanocorp primarily sold MII to customers located abroad, but also shipped MII domestically on a more limited basis.

From approximately on or about September 17, 2007 and continuing through in or around April 2009, you conspired with others to defraud the U.S. by causing Melanocorp to ship MII on a limited basis to customers in the U,S., despite having specifically told FDA that Melanocorp would not distribute or market MII in the U.S.

FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to regulation of any drug product under the Act. As described above, you admitted that Melanocorp sold MII, a drug that had not been approved by the FDA. Melanocorp marketed and advertised MII as an injectable tanning product and its website included claims that MII could reduce skin cancer

rates and could cure rosacea. Despite the FDA warning that MII could not be distributed without FDA approval, you continued to sell MII both domestically and abroad.
By knowingly selling unapproved drugs you put patients at risk and undermined FDA's regulatory oversight over drug products marketed in the United States. You circumvented FDA's regulatory authority and placed consumers' health in jeopardy. FDA finds that your felony conviction under 18 U.S.C. 371 was for conduct relating to the regulation of drug products under the Act.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(a)(2)(A) of the Act (21 U.S.C. § 335a(a)(2)(A)) permanently debarring you from providing services in any capacity to a person having an approved or pending drug product application.

In accordance with section 306 of the Act and 21 CFR Part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred as proposed in this letter.

If you decide to seek a hearing, you must file the following: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. § 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, FDA will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. You should understand that the facts underlying your conviction are not at issue in this proceeding. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2015-N-4169, and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. 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.

This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Director, Office of Enforcement & Import Operations within the Food and Drug Administration.

/s/
Sincerely,

Douglas Stearn
Director
Office of Enforcement & Import Operations