[FR Doc. 2016–27315 Filed 11–10–16; 8:45 am]
BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Information Collection: Comprehensive Child Welfare Information System

Notice

The Office of Management and Budget (OMB) has assigned approval number 0970–0463 to the Comprehensive Child Welfare Information System (CCWIS) Final Rule (81 FR 35450, published June 2, 2016) information collection. The CCWIS Final Rule describes an optional child welfare information system. States and tribes electing to build a CCWIS must collect and report certain information to the Administration for Children and Families regarding their CCWIS plans. The information collection described in the Final Rule includes:

- The automated function list (45 CFR 1355.52(i)(1)(ii)–(iii) and (i)(2))
- The data quality plan (45 CFR 1355.52(d)(5))
- The Notice of Intent (45 CFR 1355.52(i)(1))

The authority for the information collection expires on 10/31/2019 12:00:00 a.m.

Authority: 42 U.S.C. 620 *et seq.,* 42 U.S.C. 670 *et seq.;* 42 U.S.C. 1301 and 1302.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–27280 Filed 11–10–16; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–4169]

Edward Manookian (Also Known as Ed Manning): Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Edward Manookian 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. Manookian was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Mr. Manookian was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Manookian failed to request a hearing. Mr. Manookian's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective November 14, 2016.

ADDRESSES: Submit applications for special 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, Food and Drug Administration, 12420 Parklawn Dr. (ELEM–4144), Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C 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 the regulation of any drug product under the FD&C Act. On August 28, 2015, the U.S. District Court for the Middle District of Tennessee entered judgment against Mr. Manookian for two counts of conspiracy to commit an offense against the United States, in violation of 18 U.S.C. 371.

FDA's finding that the debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: Mr. Manookian was the President and owner of Melanocorp, Inc. (Melanocorp), a for-profit corporation that conducted operations in the Middle District of Tennessee, and his 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. Mr. Manookian's company advertised MII, an unapproved new drug, as an injectable tanning product through an internet Web site. The Melanocorp Web site also advertised MII as being 100 percent U.S. made, whereas in fact some of the MII sold by Melanocorp was manufactured in and imported from China.

On or about August 30, 2007, Melanocorp received a warning letter from FDA expressing concern about Melanocorp's marketing of MII. The warning letter noted that, based on information and statements on the Melanocorp Web site, MII constituted a new drug under the FD&C Act 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 FD&C Act and instructed Mr. Manookian's company to take prompt action to correct the violations cited in the warning letter.

On or about September 17, 2007, after consulting with counsel, Mr. Manookian sent a letter to FDA stating that Melanocorp had stopped all promotion and sale of MII in the United States and had stopped taking orders for MII from U.S. residents.

On or about November 29, 2007, 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 FD&C Act. The letter specifically stated that the sale of MII outside of the United States violated the FD&C Act.

On or about December 14, 2007, Mr. Manookian had a letter sent to FDA from his 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 MII to be an unapproved new drug, but Mr. Manookian's position was that Melanocorp could lawfully export MII, regardless of its status as an unapproved new drug.

On or about December 28, 2007, FDA sent a letter to Mr. Manookian's attorney which reiterated that unapproved new drugs do not qualify for export.

Following receipt of the December 28, 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 on or about September 17, 2007, and continuing through in or about April 2009, Mr. Manookian conspired with others to defraud the United States by causing Melanocorp to ship MII to customers in the United States despite telling FDA that Melanocorp would not distribute or market MII in the United States.

As a result of these convictions, FDA sent Mr. Manookian by certified mail on

August 29, 2016, a notice proposing to permanently debar him 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(a)(2)(B) of the FD&C Act, that Mr. Manookian was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. FDA determined that Mr. Manookian's felony convictions were related to the regulation of drug products because the conduct underlying his convictions undermined FDA's regulatory oversight over drug products marketed in the United States—Mr. Manookian knowingly sold unapproved drugs and put patients at risk. The proposal also offered Mr. Manookian 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 September 2, 2016. Mr. Manookian did not request a hearing 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(a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Edward Manookian has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Section 306(c)(2)(A)(ii) of the FD&C Act requires that Mr. Manookian's debarment be permanent.

As a result of the foregoing finding, Edward Manookian is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 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 201(dd) (21 U.S.C. 321(dd), 306(c)(1)(B), and (c)(2)(A)(ii) of the FD&C Act). 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 Edward Manookian, 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. Manookian 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 Edward Manookian during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Manookian for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2015–N–4169 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.

Publicly available submissions will be placed in the docket, and will be viewable at *http://www.regulations.gov* or at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 7, 2016.

Armando Zamora,

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

[FR Doc. 2016–27244 Filed 11–10–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0144]

Voluntary Qualified Importer Program; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''FDA's Voluntary Qualified Importer Program.'' The guidance describes the Voluntary Qualified Importer Program (VQIP), which provides for expedited review and importation of food offered for importation by importers who voluntarily agree to participate in the program. The guidance describes the eligibility criteria for, and benefits of, participation in VQIP. The guidance also provides information on submitting an application for VQIP participation, obtaining a facility certification for the foreign supplier of a food imported under VQIP, the VQIP user fee, conditions that might result in the revocation of VQIP eligibility, and criteria for reinstatement of eligibility.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed below (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0144 for ''FDA's Voluntary Qualified Importer Program.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets