[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