## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0471]**

### Adrien E. Aiache: Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) (the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Adrien Aiache, M.D. 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 Dr. Aiache was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. Dr. Aiache was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Aiache failed to respond. Dr. Aiache's failure to respond constitutes a waiver of his right to a hearing concerning this action.

**DATES:** This order is effective May 27, 2011.

**ADDRESSES:** Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Kenny Shade, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, 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 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 26, 2007, Dr. Aiache pleaded guilty to a misdemeanor offense of receipt in interstate commerce of a misbranded drug and delivery thereof in violation of 21 U.S.C. 331(c), 333(a)(1), and 352(f), and the United States District Court for the Central District of California entered judgment against him.

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: Dr. Aiache was a licensed physician with an office in Beverly Hills, California. In 2003, Dr. Aiache began ordering an unapproved Botulinum Toxin Type A drug, Tri-toxin, manufactured by Toxin Research International, Inc. (TRI), instead of the approved BOTOX/BOTOX Cosmetic. From on or about September 3, 2003, and continuing to on or about October 25, 2004, Dr. Aiache placed sixteen orders for a total of thirty-four vials of TRI-toxin which he had shipped from Tucson, Arizona to California. He then administered the TRI-toxin to others for the treatment of facial wrinkles. The TRI-toxin did not come with labeling or directions on how to dilute the product for injection. The TRI-toxin label stated ''for research purposes only'' and ''not for human use,'' as did the TRI invoices. Dr. Aiache admitted in an interview on May 13, 2005, that he had injected the TRI-toxin into family members, medical staff personnel, personal friends, and himself.

As a result of his convictions, on February 2, 2011, FDA sent Dr. Aiache 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)(I) of the FD&C Act, that Dr. Aiache was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Dr. Aiache 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. Dr. Aiache 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 Adrien E. Aiache has been convicted of a misdemeanor 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, Dr. Aiache 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 sections 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 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 Dr. Aiache, in any capacity during Dr. Aiache'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 Dr. Aiache 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 Dr. Aiache during his period of debarment (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B)).

Any application by Dr. Aiache for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2010–N–0471 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: May 16, 2011.

**Howard Sklamberg,**

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

[FR Doc. 2011–13196 Filed 5–26–11; 8:45 am]

**BILLING CODE 4160–01–P**