4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0377]

Scott S. Reuben: 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 permanently debarring Scott S. Reuben, M.D. 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 Dr. Reuben was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act. Dr. Reuben was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Reuben failed to respond. Dr. Reuben's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the Federal Food, Drug, and Cosmetic 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 Federal Food, Drug, and Cosmetic Act.

On June 24, 2010, the U.S. District Court for the District of Massachusetts entered judgment against Dr. Reuben for health care fraud in violation of 18 U.S.C. 1347.

The FDA's finding that debarment is appropriate is based on the felony conviction referenced herein for conduct relating to the regulation of a drug product. The factual basis for this conviction is as follows: Dr. Reuben was a physician licensed by the State of Massachusetts working as an anesthesiologist providing anesthesia services to patients in connection with surgeries, and also treating patients post-surgery in the District of Massachusetts. Dr. Reuben served as the chief of acute pain at a hospital in Western Massachusetts and maintained an office at the hospital for the purpose of conducting research. Dr. Reuben's interest, from a research perspective, was in post-operative multimodal analgesia therapy. Dr. Reuben made proposals for research funding to pharmaceutical companies that manufactured drugs that he used or proposed to use in multimodal analgesia therapy. Dr. Reuben represented to the companies that, as the principal investigator, he would be performing clinical studies with actual patients to whom he would administer the drug that was the subject of the research grant.

Dr. Reuben entered into contracts to perform research studies funded by the companies from at least as early as 1999. Dr. Reuben purported to perform the research called for by the contracts, and published articles in various medical journals based on the purported results of the research, when in fact those studies had not been performed, and therefore the research results reported in the medical journals were false.

As a result of his convictions, on August 22, 2011, FDA sent Dr. Reuben a notice by certified mail 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(a)(2)(B)), that Dr. Reuben was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act. This conclusion was based on the fact that FDA regulates clinical trials related to drug products such as those described previously as part of the Agency's regulation of drug products. The proposal also offered Dr. Reuben 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 August 26, 2011. Dr. Reuben failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has 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(a)(2)(B) of the (21 U.S.C. 335a(a)(2)(B)) of the Federal Food, Drug, and Cosmetic Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Scott S.

Reuben has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act.

As a result of the foregoing finding, Dr. Reuben is permanently debarred 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service (42 U.S.C. 262), effective (see DATES) (see section 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), 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 Dr. Reuben, in any capacity during Dr. Reuben's debarment, will be subject to civil money penalties (section 307(a)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335b(a)(6))). If Dr. Reuben 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 Federal Food, Drug, and Cosmetic 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 Dr. Reuben during his period of debarment (section 306(c)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(c)(1)(A)).

Any application by Dr. Reuben for special termination of debarment under section 306(d)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA-2011-N-0377 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: November 7, 2011.

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

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