



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1565]

Mark Reinhard: Final 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 (FD&C Act) permanently debaring Mark Reinhard 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. Reinhard was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Reinhard was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred within the timeframe prescribed by regulation. Mr. Reinhard has not responded to the notice. Mr. Reinhard's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of his right to a hearing concerning this action.

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

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM-4029), Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, or at debarments@fda.hhs.gov.

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 from providing services in any capacity to a person that has an approved or pending drug product application 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 March 28, 2019, Mr. Reinhard entered a plea of guilty to one count of engaging in unlicensed wholesale distribution of prescription drugs in violation of sections 301(t), 303(b)(1)(D), and 503(e)(1)(A) of the FD&C Act (21 U.S.C. 331(t), 333(b)(1)(D), and 353(e)(1)(A)) and (18 U.S.C. 2), a felony offense under Federal law. On January 16, 2020, judgment of conviction was entered against Mr. Reinhard for this felony offense in the U.S. District Court for the Western District of Kentucky, Louisville Division.

The factual basis for this conviction is as follows: Mr. Reinhard was a pharmacist residing in the State of West Virginia and was employed by Meds 2 Go Express Pharmacy, Inc. (Meds 2 Go Express). From November 2010 through at least August 2012, he aided and abetted others, through Meds 2 Go Express, by engaging in unlicensed wholesale distribution of Tramadol from West Virginia to Alabama through Kentucky. Specifically, Mr. Reinhard aided and abetted individuals who combined, conspired, confederated, and agreed to engage in a scheme to sell, distribute, and dispense prescription drugs over the internet and to deliver those prescription drugs to customers, without the issuance of valid prescriptions. Under this scheme, customers would order prescription drugs from websites without ever seeing or speaking to a physician or medical practitioner. On the website, customers chose which prescription drugs they wished to order, and completed an online medical questionnaire with prepopulated answers that did not disqualify the customers from receiving the prescription drugs that they ordered. The website operator would then send the completed online medical questionnaires to doctors or individuals posing as doctors, who issued the prescriptions requested by the customers without

first conducting an in-person medical examination, speaking with the customers, reviewing the customers' medical records, or otherwise verifying any of the information provided by the customer. These invalid prescriptions were issued outside of the usual course of professional practice and were not for a legitimate medical purpose. The website operators would then send the issued prescription by electronic means to pharmacies, including Meds 2 Go Express, to be filled. After filling a prescription, Meds 2 Go Express and other pharmacies would send the prescription drugs to the customers, who often were not in the same State as the pharmacy, via the U.S. Postal Service or other delivery methods. It was found that Mr. Reinhard distributed the prescription drug Tramadol from West Virginia to a wholesale fulfillment pharmacy located in Alabama through Kentucky in violation of Federal law. Tramadol, as contained in the drug product ULTRAM and generic formulations, is a prescription painkiller that may induce psychic and physical dependence.

Based on this conviction, FDA sent Mr. Reinhard by certified mail on October 5, 2020, 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. Reinhard was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Reinhard 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 file a timely request for a hearing would constitute an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Reinhard received the proposal on October 10, 2020. He did not request a hearing within the timeframe prescribed by regulation 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 Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Reinhard has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Reinhard is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see DATES) (see sections 306(a)(2)(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 in any capacity the services of Mr. Reinhard 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. Reinhard 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 application from Mr. Reinhard during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a “drug product” is defined as a drug subject to regulation 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) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Reinhard for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2020-N-1565 and sent to the Dockets Management Staff (see ADDRESSES). 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 <https://www.regulations.gov> or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: April 7, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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