4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0783]

Cheng Yi Liang: 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 (the FD&C Act) permanently debarring Cheng Yi Liang, from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Mr. Liang was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for the development or approval, of a drug product. Mr. Liang was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Liang failed to respond. Mr. Liang'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, 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)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) 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 development or approval, including the process for development or approval, of any drug product.

On March 5, 2012, the U.S. District Court for the District of Maryland accepted Mr. Liang's plea of guilty and adjudged him guilty of one count of making a false statement to a Federal Agency, a Federal felony offense under 18 U.S.C. 1001 and securities fraud, a Federal felony offense under 15 U.S.C. 78j(b) and 78ff.

FDA's finding that debarment is appropriate is based on the felony conviction for securities fraud referenced herein for conduct relating to the development or approval, including the process for development or approval, of any drug product. The factual basis for this conviction is as follows: Mr. Liang was a chemist for FDA, working in the Center for Drug Evaluation and Research (CDER) at the Office of New Drug Quality Assessment. As a part of his duties with FDA, Mr. Liang had access to the FDA's Document Archiving, Reporting and Regulatory Tracking Systems (DAARTS), which CDER used internally to manage, track, receive and report on new drug applications as well as emerging significant drug safety issues.

Between in or about July 2006 and in or about March 2011, Mr. Liang reviewed the DAARTS system to learn non-public information regarding when an FDA announcement regarding an experimental drug was imminent and to learn the substance of the announcement. Mr. Liang used this non-public information relating to drug approvals to cause the execution of

trades on national securities exchanges, resulting in total profits and losses avoided of $3,776,152 during that period of time.

As a result of his conviction, on November 6, 2012, FDA sent Mr. Liang 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)(A) of the FD&C Act, that Mr. Liang was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. The proposal also offered Mr. Liang 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 November 9, 2012. Mr. Liang 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, Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.21), finds that Cheng Yi Liang has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product.

As a result of the foregoing finding, Mr. Liang 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 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)(ii), and 201(dd) of the FD&C 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 Mr. Liang in any capacity during Mr. Liang'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 Mr. Liang 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 Mr. Liang during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Liang for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2012-N-0783 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: February 8, 2013.

Melinda K. Plaisier,
Acting Associate Commissioner for Regulatory Affairs,
Office of Regulatory Affairs.

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