DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Cheng Yi Liang/53238-037
FPC Duluth
Federal Prison Camp
P.O. Box 1000
Duluth, MN 55814

11-06-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2012-N-0783

Dear Mr Liang:

This letter is to inform you that the Food and Drug Administration (FDA or the Agency) is proposing to issue an order permanently debarring you from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that you were 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 and otherwise relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act). This letter also offers you an opportunity to request a hearing on the proposal.

Conduct Related to Conviction

On March 5, 2012, the United States District Court for the District of Maryland accepted your plea of guilty and adjudged you 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. On March 5, 2012, the court sentenced you to 60 months of imprisonment to run concurrent on both counts. The underlying facts supporting these felony convictions are as follows:

Beginning in October 1996, you were a chemist for the FDA, working in the Center for Drug Evaluation and Research (CDER) at the Office of New Drug Quality Assessment. As part of your duties with the FDA, you had access to the FDA's Document Archiving, Reporting and Regulatory Tracking Systems (DARRTS), which the CDER used internally to manage, track, receive and report on New Drug Applications (NDA) as well as emerging significant drug safety issues. The DARRTS system is an internal CDER only system which requires a secure password to access the system.

Much of the information accessible in the DARRTS system is non-public information regarding the pharmaceutical companies which had submitted drug applications to the FDA for approval. Between in or about July 2006 and in or about March 2011, you reviewed the DAARTS system to learn when an FDA announcement regarding an experimental drug was imminent and to learn the substance of that announcement. You used this non-public information 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.

In one instance, you did willfully and unlawfully, directly and indirectly, employ a device, scheme, or artifice to defraud in connection with the purchase or sale of Clinical Data, Inc.'s (Clinical Data) securities, which are sold on the NASDAQ. You admitted to knowingly using, or causing someone to use, the means or instrumentalities of interstate commerce, including the telephone, wires, mails, or the facilities of a national securities exchange in connection with the device, scheme, or artifice and you acted willfully and with the intent to defraud.

As a part of the insider trading scheme you learned that on or about May 21, 2010, the FDA accepted Clinical Data's NDA for Viibryd. The FDA set January 22, 2011 as the date by which it was required to act on the NDA under statute. This date was publicly announced by Clinical Data. As a part of your insider trading scheme, between January 6, 2011 and January 21, 2011, you regularly accessed the DARRTS system and reviewed information regarding Clinical Data's NDA for Viibryd. It was further part of the insider trading scheme that you used the names of your relatives and acquaintances to create and access numerous trading accounts that you then controlled with brokerage companies.

It was further a part of the insider trading scheme that between on or about January 6, 2011 and or about January 21, 2011 you used several accounts you controlled to purchase and cause to be purchased a total of approximately 46,875 shares of Clinical data stock at prices ranging from approximately $14.70 to approximately $15.90 per share. After the markets closed on Friday January 21, 2011, Dow Jones released news of Clinical Data's NDA approval. Clinical Data's stock price closed at approximately $15.03 per share on January 21, 2011 and opened at approximately $24.76 per share on January 24, 2011, the first day of trading after news of the NDA approval became public.

It was further a part of your insider trader scheme that on or about January 24, 2011, you used several of the accounts you controlled to sell a total of approximately 46,875 shares of Clinical Data stock, profiting by approximately $384,300.
FDA employees are required to submit annual confidential financial disclosure forms, disclosing, among other things, investment assets with a value greater than one $1000 and sources of income greater than $200. On or about February 16, 2010, in the District of Maryland and elsewhere, you in a matter within the jurisdiction of the executive branch of the government of the United States did knowingly and willfully falsify, conceal, and cover up by trick, scheme or device a material fact, by failing to disclose in your annual confidential financial disclosure filed with the FDA that, during 2009, you had earned approximately $1,040,000 from trading in stock of Vanda, a pharmaceutical company, all in violation of 18 U.S.C. § 1001.

FDA's Findings

Section 306(a)(2)(A) of the 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. FDA finds that you were convicted of a felony under Federal law for conduct relating to the development or approval of Viibryd.

You pleaded guilty to one count of securities fraud, a felony, which was committed based on inside information about FDA's approval of Viibryd. As an FDA employee who worked in CDER's Office of New Drug Quality Assessment, you had access to the DAARTS database containing non-public information about the status of approvals for new drugs. FDA is required by statute and its regulations to keep certain information relating to drug approvals confidential. You exploited the position with which you were entrusted as a scientist at FDA to access confidential information in the DAARTS database about the approval status of Viibryd, and you used that information in a scheme for personal gain. You accessed confidential information on Viibryd repeatedly as part of your scheme, and set up brokerage accounts in the names of others in furtherance of that scheme. You used your access to learn that FDA planned to approve Viibryd and caused the brokerage accounts you controlled to buy and sell shares based on that approval. Your conduct in doing so was directly tied to the approval of Viibryd and the announcement of that approval. The felony of securities fraud to which you pled guilty includes as an element of your crime that you acted willfully and with the intent to defraud.

The Standards of Ethical Conduct for Employees of the Executive Branch require that all employees shall not engage in a financial transaction using nonpublic information, nor allow the improper use of nonpublic information to further his own private interest or that of another, whether through advice or recommendation, or by knowing unauthorized disclosure. You were aware of your responsibility to comply with this requirement, and you violated that responsibility.

You also pleaded guilty to one count of making a false statement to a Federal agency by knowingly and willfully failing to disclose in your annual confidential financial disclosure filed with the FDA that you had traded in stock of a pharmaceutical company, Vanda, and that you earned approximately $1,040,000 in 2009.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under Sections 306(a)(2)(A) and 306(a)(2)(B) of the Act (21 U.S.C. 335a(a)(2)(A) and 335a(a)(2)(B)) permanently debarring you from providing services in any capacity to a person having an approved or pending drug product application.

In accordance with Section 306 of the Act and 21 C.F.R. part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file the following: (1) on or before 30 days from the

date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 C.F.R. part 12 and 306(i) of the Act (21 U.S.C. 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, the Agency will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction mandates your debarment.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2012-N-0783 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. 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.

This notice is issued under Section 306 of the Act (21 U.S.C. 335a) and under authority delegated to the Director, Office of Enforcement, Office of Regulatory Affairs (FDA Staff Manual Guide 1410.35).

Sincerely,

Reynaldo R. Rodriquez, Jr.

Reynaldo R. Rodriquez, Jr.
Acting Director,
Office of Enforcement and Import Operations
Office of Regulatory Affairs

HF-22/Matthew Warren
HFC-300/ Jeffrey Ebersole
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-300/ Ilisa Bernstein
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFD-003/Keith Webber
HFC-2/ Michael Verdi

HFD-45/Ball, Leslie
HFD-45/Constance Cullity
HFD-45/Susan K. Cummins
HFD-45/Thomas Moreno
HFD-45/Karena Cooper
HFD-45/David Burrow
HFV-200/Daniel G. McChesney

HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF