DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

MAR 0 2 2010

Ray Nathan
13734 Trento Place
San Diego, CA 92130-3174

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2010-N-0064

Dear Dr. Nathan:

This letter is to inform you that the Food and Drug Administration (FDA) 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 or about May 3, 2007, judgment was entered against you in the United States District Court for the District of Massachusetts for wire fraud, that is, for devising and executing a scheme to defraud, and to obtain money and property by means of false and fraudulent pretenses, representations, and promises, transmitted and caused to be transmitted, in interstate commerce, wire communications, including writings, signals and sounds for the purpose of executing the scheme to defraud, in violation of 18 U.S.C. 1343 and 2. The underlying facts supporting this felony conviction are as follows:

Beginning in or about June 2005, in the District of Massachusetts and elsewhere, you did with the intent to defraud, devise a scheme to obtain proprietary information from a Massachusetts pharmaceutical contract manufacturer by using the stolen identity of an employee of one of its customers.

In or about 2005, you and other founders of a start-up pharmaceutical company called Argus Therapeutics discussed the possibility of manufacturing a generic version of PhosLo, a drug manufactured by Nabi Biopharmaceuticals, a Florida company. Lyne Laboratories, in Brockton, Massachusetts, manufactured PhosLo, as a sub-contractor, for Nabi. You and others at Argus

Therapeutics agreed that one of the best ways to learn how to make the generic version of PhosLo would be to obtain a copy of the Certificate of Analysis for PhosLo. You told the other Argus Therapeutics founders that you would get a copy of the Certificate of Analysis for PhosLo.

On or about June 2, 2005, as a part of your effort to obtain a copy of the Certificate of Analysis, you did research and identified a senior Nabi employee and used his identity to fraudulently create an email account in that employee's name. On June 3, 2005, you sent a fraudulent email from this email account to a senior employee at Lyne Laboratories in an effort to obtain a copy of the Certificate of Analysis for PhosLo. When the Lyne Laboratories employee requested a physical address to which he could mail the Certificate of Analysis, you responded with an email from the fraudulent email account, asking that the Certificate be mailed to the San Diego, California address of one of the other Argus Therapeutics principals. On July 29, 2005, when you had not received the requested Certificate of Analysis, you sent another email from the fraudulent email account to Lyne Laboratories.

As a part of your plea agreement you expressly and unequivocally admitted that you in fact knowingly, intentionally and willfully committed the crime of wire fraud and are guilty of that offense.

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 your felony conviction for wire fraud was for conduct relating to the development or approval, including the process for development or approval, of a drug product because the conduct underlying the conviction related to the development of a generic version of the drug product PhosLo Tablets for FDA approval.

Section 306(a)(2)(B) of the 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 otherwise relating to the regulation of any drug product under the Act. FDA finds that the felony referred to in the plea agreement was also for conduct otherwise relating to the regulation of a drug product under the Act because it related to your development of a generic version of PhosLo Tablets, which is a drug product regulated under the Act by FDA.

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-2010-N-0064 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,

Brenda Holman
RADM, United States Public Health Service
Acting Director
Office of Enforcement
Office of Regulatory Affairs