DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 10 2007

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. 2007N-0299

Dear Dr. Norman:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debarring you for a period of 5 years 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 misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act), and the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On October 28, 2002, the United States District Court for the Western District of New York accepted your plea of guilty to one count of failure to maintain adequate and accurate records relating to the use of investigational new drugs, a Federal misdemeanor offense under 21 U.S.C. 331(e) and 333(a)(1). The basis for this offense is that 21 U.S.C. 355(i) authorizes FDA to issue regulations for the use of investigational new drugs, including regulations requiring the establishment and maintenance of records relating to the investigational use of new drugs. Consequently, under 21 CFR 312.62 (a) and (b), a clinical investigator must maintain adequate and accurate records concerning the disposition and case histories of the clinical testing of investigational new drugs. A judgment of conviction was entered against you by the United States District Court for the Western District of New York on February 5, 2003. The underlying facts supporting this misdemeanor conviction are as follows:

In 1999, FDA authorized an investigational new drug application (IND) for the clinical testing of rofecoxib, manufactured by Merck & Co. (see 21 U.S.C. 355(i)). In May 1999, Merck retained you, a licensed physician, to perform clinical testing of rofecoxib on 12 patients in your medical practice, which was located in Buffalo, New York. As a clinical

investigator, you were required by FDA regulations to conduct the study in accordance with protocols contained in the IND. You properly completed testing on six patients; but beginning in August 1999 and continuing through November 1999, you created false records for six patients that you claimed were enrolled in the second portion of the rofecoxib study. You failed to maintain accurate and adequate records of the testing of rofecoxib relating to those six patients as well as the disposition of rofecoxib designed for use in those six patients. These actions were a violation of FDA's regulations (21 CFR 312.62(a) and (b)). You knew that the records on the patients contained false information. Merck paid you approximately $1,500 for the portion of the drug study relating to those six patients.

In addition to the misdemeanor conviction, your illegal conduct as relates to the rofecoxib study led to your disqualification as a clinical investigator. Pursuant to your plea agreement, you executed an "Agreement With Respect to the Use of Investigational Drug Products." This consent agreement, among other things, disqualified you as a clinical investigator, making you ineligible to receive investigational drugs, biologics, devices, or food additives, and provided that you are not entitled to conduct any further studies of FDA-regulated investigational products intended or required for submission to the FDA. Your disqualification was based upon repeated and deliberate submissions of false information to a drug sponsor in required reports for the study of an investigational drug that is subject to section 505 of the Act (21 U.S.C. 355). In 1999, you repeatedly and deliberately failed to comply with regulations governing the conduct of clinical investigators and the use of investigational new drugs in conducting the study sponsored by Merck for rofecoxib. Among other things, you deviated from the approved protocol, failed to prepare and maintain adequate and accurate study records for certain subjects, and submitted false information to the sponsor in required reports.

FDA's Finding

Section 306(b)(2)(B)(i)(I) of the Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits the FDA to permissively debar an individual if FDA finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under the Act, if the type of conduct that is the basis for the conviction undermines the process for the regulation of drugs. Your misdemeanor conviction under 21 U.S.C 331(e) and 333(a)(1) was for illegal conduct relating to the development or approval, or process for development or approval of a drug product -- Merck's rofecoxib. As a clinical investigator conducting an IND study for a drug product, you were required to follow certain requirements set forth in section 505(i) of the Act (21 U.S.C. 355(i)) and § 312.62 (a) and (b) of FDA's regulations. Your conviction was directly related to your deviation from such requirements in conducting clinical studies on the drug rofecoxib. Your failure to comply with these provisions of the Act and FDA regulations is the type of behavior that undermines confidence in the

results of clinical studies that are relied on in the approval process for drug products, not just the studies for rofecoxib. Therefore, your conduct undermines the process for the regulation of drugs.

Under section 306(1)(2) of the Act (21 U.S.C. 335a(1)(2)), permissive debarment may be applied when an individual is convicted within 5 years preceding this notice. Under 306(l)(1), for purposes of debarment, a person is considered to have been convicted when a judgment of conviction has been entered against the person by a Federal or State court or when a plea of guilty by the person has been accepted by a Federal or State Court. You were convicted when your guilty plea was accepted on October 28, 2002, less than 5 years ago. Under section 306(c)(2)(A)(iii) of the Act (21 U.S.C. 335a(c)(2)(A)(iii)), the period of a debarment proposed under section 306(b)(2) (21 U.S.C. 335a(b)(2)) shall not be more than 5 years.

Section 306(c)(3) of the Act (21 U.S.C. 335a(c)(3)) provides several factors for consideration in determining the appropriateness of and the period of permissive debarment. The factors applicable here include: (1) nature and seriousness of the offense involved, (2) nature and extent of management participation in any offenses, (3) nature and extent of voluntary steps to mitigate the impact on the public, and (4) prior convictions involving matters within the jurisdiction of the FDA.

1. Nature and seriousness of the offense involved.

You were convicted of one count of failure to maintain adequate and accurate records relating to the use of investigational new drugs based on your submitting false information in required reports to the sponsor of rofecoxib, which you were studying for the treatment of osteoarthritis.

The Agency finds that your conduct in knowingly creating fraudulent study data and submitting the data to the drug sponsor in required reports undermined the process for the development of drugs under the Act. The information you falsified is the type that affects FDA's regulatory decisions about drug products. In addition, the creation and submission of the falsified data potentially undermined the determination of safety, effectiveness, and quality of rofecoxib that the drug's study protocol was designed to assess. Accordingly, the Agency considers the nature and seriousness of the conduct underlying your conviction as an unfavorable factor.

2. Nature and extent of management participation in any offense.

As the principal investigator and sole individual responsible for the conduct of the rofecoxib IND study that you were retained to perform, you were in a position of authority to plan, direct, or initiate the conduct underlying your conviction. You admitted that you repeatedly and deliberately failed to conduct the clinical study in accordance with the study protocol, fabricated data on the study to conceal such conduct, and

submitted the fraudulent data to the sponsor of the drug in required reports. Therefore, the Agency considers the nature and extent of your management participation as an unfavorable factor.

3. Nature and extent of voluntary steps to mitigate the impact on the public.

In your capacity as a clinical investigator, you were required to comply with certain requirements set forth in the Act and regulations. You admitted that you were aware of these requirements. However, you repeatedly and deliberately deviated from such requirements in conducting the study. Specifically, the violations you committed included, among other things: reporting the enrollment of nonexistent subjects in the study on rofecoxib, fabricating all of the pertinent study records associated with these subjects, failing to conduct the study according to the approved protocol, and falsely identifying blood and urine samples submitted to the laboratory for analysis. You took no steps to mitigate the reliance on this false information in the drug approval process. Instead, you received financial gain in exchange for the conduct underlying your conviction. Therefore, the Agency considers the nature and extent of mitigation as an unfavorable factor.

4. Prior convictions.

The Agency is unaware of any additional criminal convictions.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(b)(2)(B) of the Act (21 U.S.C. 335a(b)(2)(B)) debarring you from providing services in any capacity to a person that has an approved or pending drug product application for a period of 5 years. You were convicted of one count of failure to maintain adequate and accurate records relating to the use of investigational new drugs, a Federal misdemeanor involving conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under the Act. In addition, FDA has found that the type of conduct which served as the basis for your conviction undermines the process for the regulation of drugs. 306(b)(2)(B)(i)(I) of the Act (21 U.S.C. 335a(b)(2)(B)(i)(I)). The Agency proposes a 5-year debarment period for the offense based on the factors discussed above.

In accordance with section 306 of the Act (21 U.S.C. 335a) and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred as proposed in this letter.

If you decide to seek a hearing, you must file: (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 CFR part 12 and section 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 supports your debarment under section 306(b)(2)(B) of the Act (21 U.S.C. 335a(b)(2)(B)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 2007N-0299 and sent to the Division of Dockets Management (HFA-305), 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 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) and under authority delegated to the Director of the Center for Drug Evaluation and Research (Staff Manual Guide 1410.35).

Sincerely,

Janet Woodcock, M.D.
Acting Director
Center for Drug Evaluation and Research