



MAY 6 2002

Food and Drug Administration
Rockville MD 20857

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Elaine Yee-Ling Lai
17200 Monaco Drive
Cerritos, CA 90703

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 00N-1529

Dear Ms. Lai:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debaring 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. The FDA bases this proposal on a finding that you were convicted of a felony for aiding and abetting the making of a false document containing a materially fictitious statement in a matter within the jurisdiction of a government agency, and that your conduct undermined the process for the regulation of drugs. This letter also offers you an opportunity for a hearing on the proposal.

Conduct Related to Debarment

On June 9, 1998, the United States District Court for the Central District of California accepted your plea of guilty to one count of aiding and abetting the making of a false document containing a materially fictitious statement in a matter within the jurisdiction of a government agency, in violation of 18 U.S.C. sections 1001(a)(3) and 2. The underlying facts supporting this felony conviction are as follows:

You were employed by American Pharmaceutical Research, Inc., formerly known as Southern California Research Institute (collectively SCRI), as the Chief Operating Officer from about March 1996 through March 1997. SCRI was a private company retained by drug manufacturers to conduct clinical studies of new pharmaceutical products to be submitted to FDA in support of approval of the drug products. Dr. Robert A. Fiddes was the owner and president of SCRI and the principal investigator for all drug research conducted at SCRI.

In April 1996, SCRI was hired to conduct a study on a drug product known as Eprosartan 090. The study protocol for this drug required that subjects possess a certain level of proteinuria in their urine to be eligible to participate in the study. Because it was difficult to enroll subjects with the required proteinuria levels, Dr. Fiddes paid an SCRI study coordinator whose urine had

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the required proteinuria levels for the use of her urine. Dr. Fiddes substituted the urine of the study coordinator for the urine of otherwise ineligible subjects so that those subjects could be enrolled in the study. You were aware that Dr. Fiddes was paying the study coordinator for the use of her urine and of the improper urine substitution.

From about June 1996 to August 1996, you knowingly and willfully assisted Dr. Fiddes in making a fraudulent document that contained false and fictitious material statements and entries. Specifically, to conceal the urine substitution from the FDA, you assisted Dr. Fiddes in creating a false subject chart for the study coordinator to make it appear that she was a subject of Dr. Fiddes and was submitting her urine in connection with treatment by Dr. Fiddes. You assisted in creating the fraudulent document with the intent to influence FDA's decision about the Eprosartan 090 drug study.

FDA's Finding

Section 306(b)(2)(B)(i)(II) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits the FDA to debar an individual if it finds that the individual has been convicted of a felony under Federal law for conspiracy to commit, or aiding or abetting a criminal offense relating to the development or approval, including the process for the development or approval, of any drug product, or otherwise relating to the regulation of drug products under the Act and that the offense undermines the process for the regulation of drugs. Your felony conviction under 18 U.S.C. sections 1001(a)(3) and 2 was for aiding and abetting in making fraudulent documents and statements for use by FDA to determine whether a new drug should be approved, an offense related to the development or approval of any drug product. Accordingly, the Agency finds that you are eligible for permissive debarment.

Under section 306(l)(2) of the Act, permissive debarment may be applied when an individual is convicted within the 5 years preceding this notice. You were convicted on June 9, 1998, less than 5 years ago. The Agency may debar you for up to 5 years for each offense, and can determine whether the debarment period for multiple offenses shall run concurrently or consecutively (306(c)(2)(A) of the Act) (21 U.S.C. 335a(c)(2)(A)).

Section 306(c)(3) of the Act provides six factors for consideration in determining the appropriateness of and the period of permissive debarment for a person (21 U.S.C. 335a(c)(3)). These are as follows:

- (A) the nature and seriousness of any offense involved,

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(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

(F) prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

The Agency considers that four of these factors are applicable for consideration:

1. The nature and seriousness of the offense involved (Factor A)

You were convicted of one count of aiding and abetting the making of a materially false document based on your assistance in fabricating a subject chart to conceal study protocol violations involving the drug Eprosartan 090, which was being studied for the treatment of diabetes and hypertension.

The Agency finds that your conduct undermined the integrity of the drug approval or regulatory process. You knowingly assisted in creating fraudulent study data to be used by FDA in determining whether to approve Eprosartan 090. Your illegal conduct was intended to affect FDA's regulatory decision about the drug. Accordingly, the Agency will consider the nature and seriousness of your conduct an unfavorable factor.

Further, diabetes and hypertension are serious and potentially life-threatening diseases. Accordingly, the Agency will consider your conduct an extremely unfavorable factor because your actions potentially undermined the safety or effectiveness of a drug used for a serious or life-threatening condition.

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2. The nature and extent of management participation in any offense involved whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense (Factor B)

You participated in the planning of the conduct underlying the conviction. You knew of the improper urine substitutions and helped Dr. Fiddes to falsify records to conceal the misrepresentations from the FDA. Accordingly, the Agency considers the nature and extent of your participation an unfavorable factor.

3. The nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health (Factor C)

You did not disclose to appropriate authorities all wrongdoing, and in fact took affirmative actions to conceal wrongdoing. Further, you did not report drug related violations nor did you take action to correct violations although you knew that the actions were violative of the law. Therefore, the Agency will consider the nature and extent of mitigation as an unfavorable factor.

4. Prior convictions under this Act or under other Acts involving matters within the jurisdiction of the Food and Drug Administration (Factor F)

The Agency is unaware of any prior convictions.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, the FDA proposes to issue an order under section 306(b)(2) of the Act, debarring you from providing services in any capacity to a person that has an approved or pending drug product application for one period of 5 years. You were convicted of one count of aiding and abetting the making of a false document containing a materially fictitious statement in a matter within the jurisdiction of a government agency, a felony described in section 306(b)(2)(B)(i) and (a)(2). Since you were convicted of one count, FDA finds you committed one offense. The Agency intends to implement the maximum debarment period for the offense, based on the factors discussed above.

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In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given an opportunity for 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 a hearing, notice of appearance and request for a hearing, information and analyses to justify a hearing, and determination of 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 on 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 the 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. 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 enter summary judgment against you, making findings and conclusions, and denying a hearing.

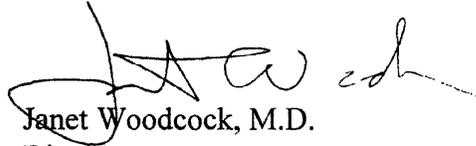
You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction permits your debarment as proposed.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 00N-1529 and sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. You must file four copies of all submissions under 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

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This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 306 (21 U.S.C. 335a)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.99).

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Janet Woodcock', with a stylized flourish at the end.

Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research