DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 27 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard Elliott Humphreys
13021 Maple Springs Drive
Fredericksburg, VA 22408

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 00N-1525

Dear Mr. Humphreys:

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 regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act). This letter also offers you an opportunity for a hearing on the proposal.

Conduct Related to Conviction

On July 15, 1996, you pled guilty to one count of making false statements to an agency of the United States, a Federal felony offense under 18 U.S.C. 1001. On October 6, 1996, the United States District Court for the Eastern District of Virginia sentenced you for this offense. The underlying facts supporting this felony conviction are as follows:

At the time of your criminal actions, you were Vice President of Pat Grimes, Inc., a company which, among other things, transfills and repackages compressed medical gas, such as oxygen, from bulk into aluminum cylinders for medicinal use.

Under the Act and FDA's implementing regulations, Pat Grimes, Inc., was responsible for manufacturing and repackaging the oxygen in compliance with current good manufacturing practices (CGMPs) to ensure, among other things, that the oxygen was unadulterated.

On February 2, 1994, FDA inspected the Pat Grimes facility. FDA's inspection revealed that the firm was manufacturing oxygen for medicinal use with significant CGMP deficiencies, including, but not limited to, failure to document a batch filling log, failure to document purity testing, improperly documenting labels as to lot numbers and transfilling forms, and failure to document written records of gauge calibrations. In response, you agreed to recall the violative oxygen tanks and sent a draft recall letter to FDA for comment. In the letter to be sent to patients you indicated that the tanks were filled improperly and offered to exchange them without charge.

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In a Warning Letter dated March 4, 1994, the FDA informed you that the improper packaging of the oxygen tanks resulted in adulterating the oxygen in violation of section 501(a)(2)(B) of the Act (21 U.S.C. section 351(a)(2)(B)). Thereafter, you knowingly made false statements and representations to FDA by stating that you were conducting a recall of adulterated compressed medical oxygen tanks, when you knew that you were not contacting patients to recall the tanks.

FDA's Finding

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 relating to the regulation of any drug product under the Act. Your felony conviction under 18 U.S.C. 1001 for making false statements and representations to FDA concerning a recall of compressed medical oxygen tanks is related to the regulation of a drug product under the Act. Your illegal acts leading to this conviction are a direct violation of the primary legislation regulating drugs.

Under 306(l)(2) of the Act (21 U.S.C. 335a(1)(2)), debarment is mandatory for an individual convicted up to 5 years prior to this notice. 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 section 306(a)(2)(B) of the Act 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 CFR part 12, you are hereby given an opportunity for a hearing to show why you should not be debarred.

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 the action proposed, and a waiver of any contentions concerning your debarment. 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.

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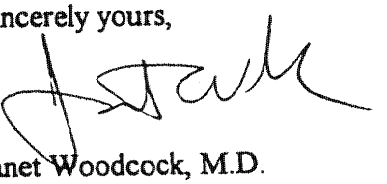
A request for hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the information and factual analyses in your request for hearing that there is no genuine and substantial issue of fact which 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 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. 00N-1525 and sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. 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.

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,



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