DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Seth M. Yoser
Register Number 23055-076
FCI Memphis
Federal Correctional Institution
P.O. Box 34550
Memphis, TN 38134

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. FDA-2010-N-0139

Dear Dr. Yoser:

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 to request a hearing on the proposal.

Conduct Related to Conviction

On February 18, 2010, the United States District Court for the Western District of Tennessee accepted your plea of guilty, and on February 23, 2010, entered judgment against you for ten counts of mail fraud in violation of 18 U.S.C. 1341; twenty-two counts of unlicensed wholesale distribution of prescription drugs in violation of 21 U.S.C. 331(t), 333(b)(1)(D), and 353(e)(2)(A); and two counts of wire fraud in violation of 18 U.S.C. 1343. The underlying facts supporting the felony convictions relevant to this Proposal to Debar are as follows.

You were employed by the Eye Speciality Group (ESG), formerly known as the Vitreorentinal Foundation, and you were a partner of ESG from in or about June, 2005, until approximately May, 12, 2008. During the course of your employment and partnership with ESG, you performed treatments which included administering the prescription drugs Visudyne and Lucentis to treat Wet Aged Macular Degeneration.

Beginning on or about July 1, 2002, and continuing up to and including May 12, 2008 you did knowingly devise a scheme and artifice to defraud ESG and Medicare in order to obtain money and property by means of false and fraudulent representation, billings, and pretense.

Beginning in or about April 14, 2004, through on or about October 2, 2007, in the Western District of Tennessee, and elsewhere, you did knowingly engage in or cause the wholesale distribution in interstate commerce of the prescription drugs, Visudyne and Lucentis in states without being licensed by those states in violation of Title 21 U.S.C. 331(t), 333(b)(1)(D), and 353(e)(2)(A).

FDA's Findings

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 a drug product under the Federal Food, Drug, and Cosmetic Act. FDA finds that your felony conviction's for unlicensed wholesale distribution of prescription drugs is sufficient to support debarment for conduct relating to the regulation of a drug product under the Act because the unlicensed distribution of prescription drugs is prohibited by the Act.

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 (21 U.S.C. 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 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 mandates your debarment under section 306(a)(2)(B) of the Act (21 U.S.C. 335a(a)(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. FDA-2010-N-0139 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 Federal Food, Drug, and Cosmetic 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
Acting Director
Office of Enforcement
Office of Regulatory Affairs

cc:
HF-3/Judge Davidson
HFC-130/Michael Rogers
HFC-300/ Jeffrey Ebersole
HFA-305 (Docket No. FDA-2010-N-0139)
GCF-1/ Seth Ray
HFM-100
HFD-1/Dr. John Jenkins, Rm. 6304, WO22
HFD-7/ Nancy Boocker
HFD-300/ Deborah Autor
HFD-310/Ann Metayer
HFD-45/Constance Lewin
HFC-2/ Michael Verdi
HFC-230/Debarment File
HFC-230/CF
HFC-200/CF