

Food and Drug Administration  
Rockville MD 20857CERTIFIED MAIL  
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JUL 18 2002

Edwin Kokes  
3210 E. Gregory St.  
Grand Island, Nebraska 68801**PROPOSAL TO DEBAR**  
**NOTICE OF OPPORTUNITY FOR HEARING**  
**Docket No. 01N-0539**

Dear Mr. Kokes:

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 pled guilty to one count 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 Debarment

On September 22, 1997, you pled guilty to one count of mail fraud, a Federal felony offense under 18 U.S.C. 1341. The United States District Court for the District of Nebraska accepted this plea on May 7, 1998. On August 19, 1998, you were adjudged guilty of this count and were sentenced by the United States District Court for the District of Nebraska. The underlying facts supporting this felony conviction are as follows:

From 1989 to 1996, you were owner and president of Independent Testing Labs. During that time, you defrauded patients by claiming to be able to diagnose medical conditions based upon analysis of hair or fingernail samples at your laboratory. You admitted that you are not a licensed physician, chiropractor, or osteopath. You also represented to patients that you could treat and cure various diseases, including cancer and AIDS, by the use of unapproved drug products that you sold and/or by the medical treatments that you performed on patients during office visits. One such unapproved drug product that you sold to patients for medical treatment was M-Bone, a product containing diluted sulfuric acid.

Under the Act and FDA's implementing regulations, new drug products for use in humans must be evaluated by FDA for safety and effectiveness through the submission of a new drug application (NDA) and must be approved by FDA before their marketing and sale to patients (see 21 U.S.C. 321 and 355 and 21 CFR Parts 310, 314, and 330).

01N-0539

NPH 1

Edwin Kokes  
Docket No. 01N-0539

### FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. 335a(a)(2)(B)) requires FDA to debar 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. Your guilty plea for one count of mail fraud under 18 U.S.C. 1341 was for illegal conduct relating to the regulation of drug products. Your health care fraud scheme involved the illegal sale of unapproved drug products to patients. Under section 306(a)(2) of the Act, your debarment is mandatory. 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) of the Act permanently debarring you from providing services in any capacity to a person that has an approved or pending drug product application.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given notice of 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 relied on to justify a hearing. The procedures and requirements governing formal evidentiary hearings as applied to debarments 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 a waiver of your right to a hearing. 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.

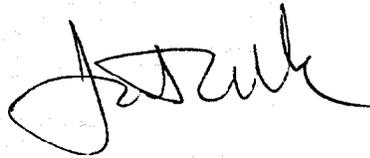
You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction mandates your debarment.

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Docket No. 01N-0539

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 01N-0539 and sent to the Dockets Management Branch (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 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,

A handwritten signature in black ink, appearing to read "J. Woodcock", written in a cursive style.

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