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Food and Drug Administration
Rockville MD 20857

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James T. Kimball
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Yazoo City, MS 39194

**PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 2005N-0105**

Dear Mr. Kimball:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debarbing 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 felonies 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 May 24, 2000, a jury found you guilty of one count of conspiring to commit offenses against the United States and the Florida Department of Health, a Federal felony offense under 18 U.S.C. 371; six counts of distributing a misbranded drug into interstate commerce, a Federal felony offense under 21 U.S.C. 331(a); and one count of making a false statement in a matter within the jurisdiction of a Federal agency, a Federal felony offense under 18 U.S.C. 1001. On October 19, 2000, the United States District Court for the Middle District of Florida entered judgment and sentenced you for these offenses. The underlying facts supporting these felony convictions are as follows:

You were a businessman engaged in the manufacture, promotion, sale, and distribution of deprenyl, among other drugs and chemical formulations. Your business, Discovery Experimental and Development, Inc. (Discovery), was located in Wesley Chapel, Florida. Gaylord Hughes was your employee, and his duties included the shipment of deprenyl and the collection of money from deprenyl customers.

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Deprenyl, or liquid deprenyl citrate, contains the active ingredient selegiline, which is also the active ingredient in Eldepryl, a prescription drug approved by FDA for treating Parkinson's disease. If dispensed without a prescription issued by a licensed practitioner, deprenyl or selegiline is misbranded. Selegiline has been reported to cause significant adverse reactions, including severe toxicity when used in combination with certain antidepressant drugs, or when used to excess in combination with certain foods and beverages.

On November 29, 1991, you, through your company Discovery, submitted two new drug applications (NDAs) to FDA for deprenyl for the treatment of Alzheimer's disease (NDA 20-242) and for "quality of life" (NDA 20-244), proposing that the drug product be marketed without a prescription for both indications. FDA notified you on or about January 17, 1992, that the applications could not be reviewed because they failed to contain necessary information required by law for FDA approval. On or about October 16, 1992, you informed FDA that you were "manufacturing deprenyl in Mexico on the borderline of the law."

FDA held an informal conference with you at its Rockville, Maryland, headquarters on or about November 16, 1992. At the conference, FDA informed you that the safety and effectiveness of deprenyl had to be demonstrated by adequate and well-controlled studies. On or about August 20, 1993, FDA notified you in writing that NDA 20-242 was not approvable for over-the-counter use for the treatment of Alzheimer's disease.

Before submitting your new drug applications to FDA, you had begun marketing deprenyl. Beginning about August 1990 and continuing for approximately a 10-year period, you, with Gaylord Hughes and others, knowingly and willfully conspired to commit offenses against the United States by engaging in illegal activities to circumvent FDA's regulatory requirements governing the manufacture and distribution of deprenyl. According to an unsealed indictment, you were involved in, among other things, the following activities related to the conspiracy:

- On or about August 1, 1990, you met with a chemist and offered him shares of stock in Discovery in exchange for his assistance in synthesizing selegiline. You caused selegiline freebase to be synthesized in Discovery's laboratory in Wesley Chapel, Florida, and further caused liquid deprenyl citrate to be formulated, bottled, labeled, and offered for interstate distribution to the general public without a prescription and without the required cautionary statement on the drug's label.
- You caused the publication and distribution of a promotional newspaper, "Inside Health," which advertised deprenyl and other Discovery products for sale, and provided instructions on how to order deprenyl. In an edition of "Inside Health," you claimed that deprenyl was "An Anti-aging Aphrodisiac."

- You opened bank accounts in the names of business entities controlled by you into which you deposited the proceeds of deprenyl sales; and, until about June 1999, you distributed deprenyl through the United Parcel Service, using post office boxes and office suites in different states to conceal and disguise the true nature of your business operation.
- Beginning about 1997, you illegally promoted and distributed deprenyl through a foreign corporation self-styled “an innovative supplier of the world’s latest commercially available medication,” namely International Antiaging Systems, Ltd., Guernsey, Channel Islands, Great Britain.
- On or about June 29, 1999, you knowingly and willfully made false statements to the United States Customs Service in connection with a parcel for export to England. You represented on a commercial invoice that the parcel contained “Liquid Dietary Vitamin Supplement – Silver 1500 pp,” when in fact, you knew the parcel contained deprenyl and Cellstat ch. The latter claimed on its label to inhibit “all three stages of cancer.”

On May 24, 2000, a jury found you guilty of eight counts of an eight-count indictment on charges of conspiracy, misbranding, and false statements in connection with the unlawful distribution of deprenyl. Based on this jury verdict, the court entered a judgment and sentenced you for these offenses on October 19, 2000.

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 convictions under 18 U.S.C. 371, 21 U.S.C. 331(a), and 18 U.S.C. 1001, were for illegal conduct relating to the regulation of drug products. The fraudulent and misleading conduct underlying your convictions under 18 U.S.C. 371 and 21 U.S.C. 331(a) involved the distribution in interstate commerce of a misbranded drug. Your conviction under 18 U.S.C. 1001 was for making false statements about a misbranded drug intended for export. Your illegal acts concerning this drug product and resulting in this conviction are a direct violation of the primary legislation regulating drugs.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

James T. Kimball
Docket No. 2005N-0105

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 debaring 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 to request 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 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.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 2005N-0105 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.

James T. Kimball
Docket No. 2005N-0105

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

Sincerely,

A handwritten signature in black ink, appearing to read "Steven Galson". The signature is written in a cursive style with a large initial "S".

Steven K. Galson, M.D., M.P.H.
Acting Director
Center for Drug Evaluation and Research