DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Resea
1401 Rockville Pike
Rockville MD 20852-1448

August 31, 2001

1953 '01 SEP -5 P1:36

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Craig H. Petrik
26751 Dominion Way
San Juan Capistrano, California 92675

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
Docket No. 01N-0359

Dear Mr. Petrik:

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, including but not limited to a biologics license application. FDA bases this proposal on its finding that your 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 January 19, 2001, the United States District Court for the Central District of California accepted your plea of guilty and entered a judgment against you for one count of making a false statement to a government agency, a Federal felony under 18 U.S.C. 1001.

According to the plea agreement, between June 23, 1997, and September 3, 1997, the FDA conducted an inspection of BioSera, Inc. During the inspection, you knowingly and willingly submitted to FDA investigators a document containing materially false statements for the purpose of influencing the result of the FDA inspection of BioSera, Inc. You submitted a disposition log of red blood cells used to stimulate a donor's antibody response identifying that three vials of red blood cells were used to stimulate donors when you knew at the time the document was submitted that one of the vials had been used for testing and the other two vials did not exist. Thus, you knew that these vials were not used to immunize plasma donors as stated in the disposition log. This was material because the FDA relies on this information to identify and locate, if necessary, the plasma donors who have been injected with red blood cells from a particular unit of blood. Moreover, you knew that FDA regulations require maintenance of accurate and correct records relating to the disposition of red blood cells.

01N-0359 LET 1

FDA's Finding

We find that you have been convicted of a felony under Federal law, 18 U.S.C. 1001, for conduct relating to the regulation of a blood product. Under sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the Act, 21 U.S.C. §§ 335a(a)(2)(B) and 335a(c)(2)(A)(ii), debarment is mandatory and permanent for an individual found convicted of a felony under Federal law for conduct relating to the regulation of any drug product.

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 that has an approved or pending drug product application, including but not limited to a biologics license application. The proposed debarment action will not affect your conviction or the terms of your plea agreement.

In accordance with section 306 of the Act and Title 21, Code of Federal Regulations (21 CFR) Part 12, by this letter you are given notice of an opportunity for a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file on or before 30 days from the date of receipt of this letter, a written request for hearing and objections. The regulations regarding a request for hearing are set forth at 21 CFR Part 12.

Your failure to file a timely written request for hearing would constitute a waiver of objections concerning your debarment. If you do not request a hearing in the manner prescribed by the regulations, the agency will deny your request for a hearing and issue a final order.
A request for hearing based on mere allegations, denials, or general descriptions of positions and contentions will not be granted. Nor will a hearing be granted on issues of policy or law. To obtain a hearing, you must present specific facts showing that there is a genuine and substantial issue of fact.

The facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted of a felony under Federal law for conduct relating to the regulation of a blood product.

Your request for a hearing, including any material submitted in support of any objection, must be identified with Docket No. 01N-0359, and sent to: Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1061, 5630 Fishers Lane, Rockville, Maryland, 20852. Please 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 Part 10.20(j). Publicly available submissions may be examined in the Dockets Management Branch office between 9 a.m. and 4 p.m., Monday through Friday.

Sincerely,

Kathryn C. Zoon, Ph.D.
Director
Center for Biologics Evaluation and
Research

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MAIL

Mr. Craig H. Petrik
26751 Dominion Way
San Juan Capistrano, CA 92675

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1. Article Addressed to:

Mr. Craig H. Petrik
26751 Dominion Way
San Juan Capistrano, CA 92675

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