

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0359]

Craig H. Petrik; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Craig H. Petrik 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 order on a finding that Mr. Petrik was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. After being given notice of his proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, Mr. Petrik failed to request a hearing. Mr. Petrik's failure to request a hearing is deemed a waiver of his right to a hearing concerning this action.

DATES: This order is effective [insert date of publication in the FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food

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DMB
Display Date 4-29-02
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Certifier R. WEDSMA

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and Drug Administration, 5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Stephen M. Ripley,
Center for Biologics Evaluation and Research (HFM-17),
Food and Drug Administration,
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Rockville, MD 20852-1448,
301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

On January 19, 2001, the U.S. District Court for the Central District of California accepted a plea of guilty and entered a judgment against Mr. Petrik for one count of making a false statement to a government agency, a Federal felony under 18 U.S.C. 1001. As a result of this conviction, FDA sent a letter dated August 31, 2001, to Mr. Petrik proposing to issue an order to permanently debar him 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, and offering him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) and (c)(2)(A)(ii) of the act (21

U.S.C. 355a(a)(2)(B) and (c)(2)(A)(ii)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Petrik was provided 30 days to file objections and request a hearing. Mr. Petrik did not request a hearing. His failure to request a hearing constitutes a waiver of his right to a hearing concerning the proposed order.

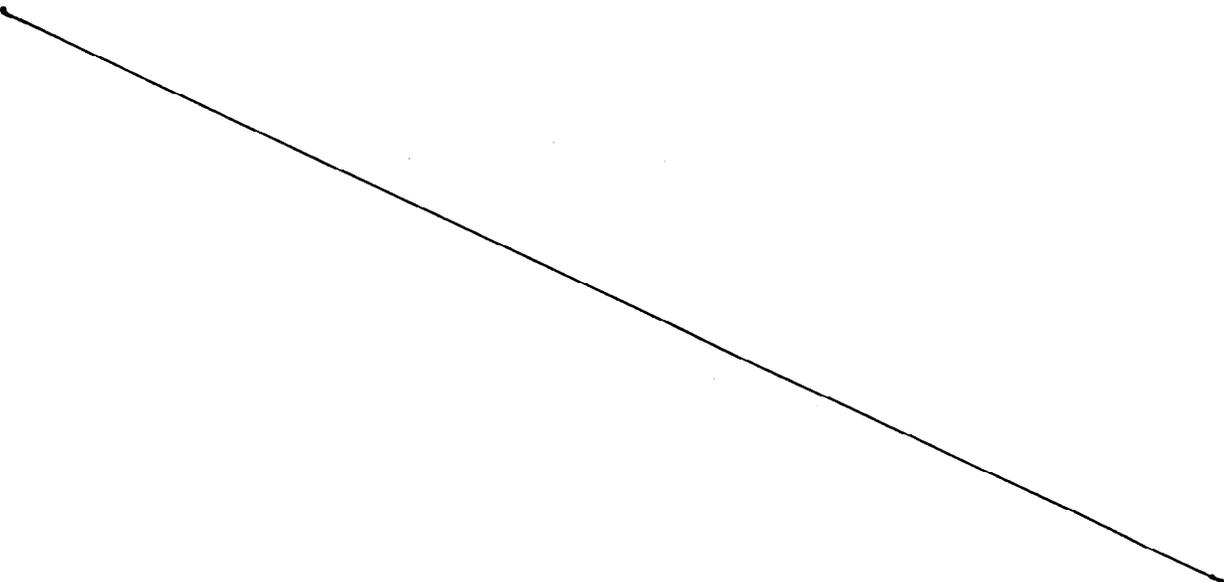
II. Findings and Order

Therefore, the Director, Center for Biologics Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Craig H. Petrik has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Mr. Craig H. Petrik is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application. A drug product means a drug, including a biological product, subject to regulation under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or section 351 of the Public Health Service Act (42 U.S.C. 262), effective [insert date of publication in the FEDERAL REGISTER] (21 U.S.C. 335a(a)(2), (c)(1)(B), and (c)(2)(A)(ii), and 321(dd)). Any person with an approved

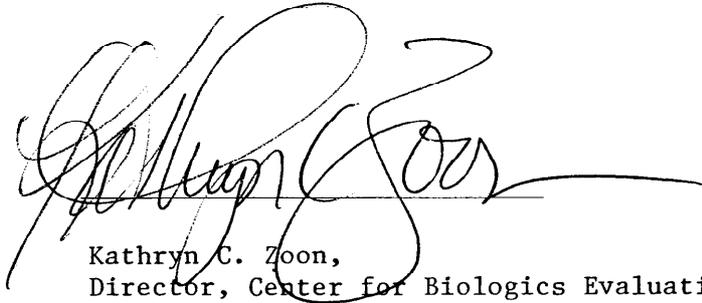
or pending drug product application including, but not limited to, a biologics license application, who knowingly uses the services of Mr. Petrik, in any capacity, during his period of debarment, will be subject to civil money penalties (21 U.S.C. 335a(a)(6)). If Mr. Petrik, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application including, but not limited to, a biologics license application, he will be subject to civil money penalties (21 U.S.C. 335a(a)(7)).

Any application by Mr. Petrik for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 01N-0359 and sent to the Dockets Management Branch (see ADDRESSES). All such submissions are to be filed in four copies (§ 10.20(a) (21 CFR 10.20(a))). The public availability of information in



these submissions is governed by § 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 (§ 10.20(j)(1)).

Dated: 4/10/02
April 10, 2002.



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

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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