

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0018]

Anne L. Butkovitz; 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 debarment Ms. Anne L. Butkovitz 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 Ms. Butkovitz was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product under the act. After being given notice of the proposed permanent debarment and her opportunity to request a hearing within the timeframe prescribed by regulation, Ms. Butkovitz failed to request a hearing. Ms. Butkovitz's failure to request a hearing constitutes a waiver of her right to a hearing concerning this action.

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

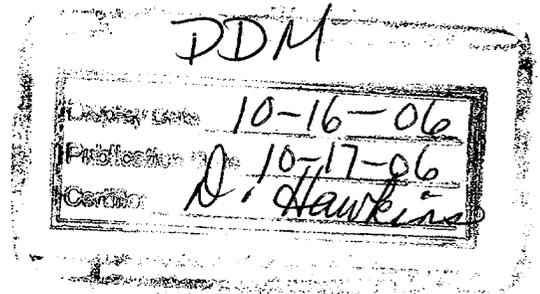
ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Brenda R. Friend,

Center for Biologics Evaluation and Research (HFM-17),

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Food and Drug Administration,
1401 Rockville Pike,
Rockville, MD 20852-1448,
301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

On June 7, 2005, the U.S. District Court for the District of Massachusetts accepted Ms. Anne L. Butkovitz's plea of guilty to one count of making a false statement, a Federal felony offense under 18 U.S.C. 1001. This offense was committed while Ms. Butkovitz was the clinical study coordinator at a safety site for a clinical trial.

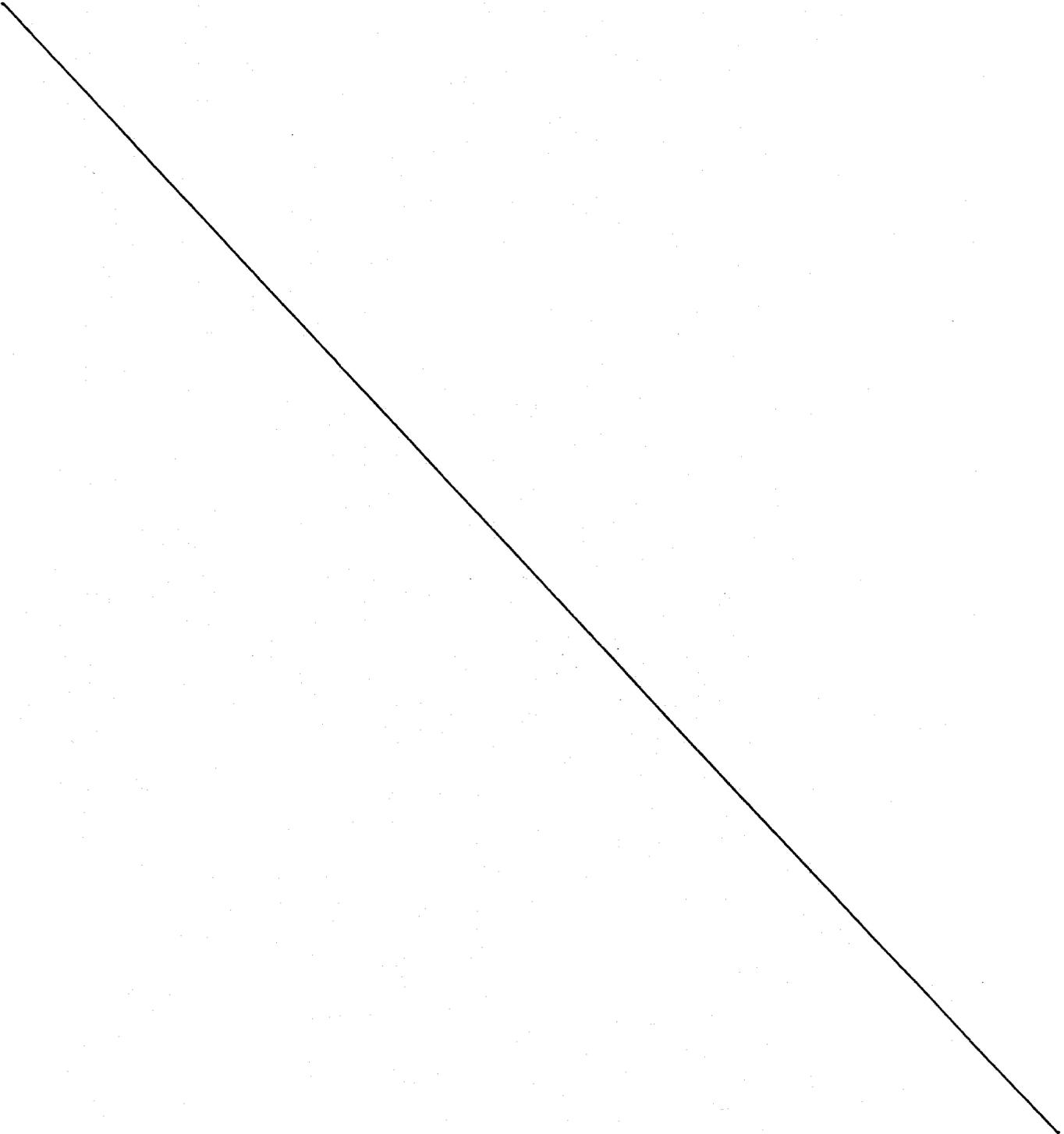
As a result of this conviction, FDA served Ms. Butkovitz by certified mail on March 7, 2006, a notice proposing to permanently debar Ms. Butkovitz from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. The proposal also offered Ms. Butkovitz an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(A) and (c)(2)(A)(ii) of the act (21 U.S.C. 335a(a)(2)(A) and (c)(2)(A)(ii)), that Ms. Butkovitz was convicted of a felony under Federal law for conduct relating to the development or approval of a drug product, including the process for development or approval, of a drug product. Ms. Butkovitz was provided 30 days to file objections and request a hearing. Ms. Butkovitz did not request a hearing. Ms. Butkovitz's failure to request a hearing constitutes a waiver of her opportunity for a hearing and a waiver of any contentions concerning her debarment (21 CFR 12.22(b)(1)).

II. Findings and Order

Therefore, the Director of the Center for Biologics Evaluation and Research, under section 306(a)(2)(A) of the act, and under authority delegated to the Director (FDA Staff Manual Guide 1410.35), finds that Ms. Butkovitz has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product.

As a result of the foregoing finding, Ms. Butkovitz is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application (section 306(c)(1)(B) of the act). 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 under section 351 of the Public Health Service Act (42 U.S.C. 262). Any person with an approved or pending drug product application including, but not limited to, a biologics license application, who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Ms. Butkovitz, in any capacity, during Ms. Butkovitz's permanent debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Ms. Butkovitz, during her permanent 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, Ms. Butkovitz will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Butkovitz during Ms. Butkovitz's permanent debarment (section 306(c)(1)(B) of the act).

Any application by Ms. Butkovitz for termination of debarment under section 306(d)(4) of the act should be identified with Docket Number 2006N-0018 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies (21 CFR



10.20(a)). 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 (21 CFR 10.20(j)(1)).

Dated: 9/25/06
September 25, 2006.



Jesse Goodman,
Director,
Center for Biologics Evaluation and Research.

[FR Doc 06-????? Filed ??-??-06; 8:45 am]
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COPY OF THE ORIGINAL

