

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000N-1427]

DMS  
Display Date 9-29-03  
Publication Date 9-30-03  
Certifier R. LEDESMA

Edmund J. Striefsky; 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 Edmund J. Striefsky from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Striefsky was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Striefsky failed to request a hearing and, therefore, has waived his opportunity for 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:

Mary Catchings,

2000N-1427

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Center for Drug Evaluation and Research (HFD-7),  
Food and Drug Administration,  
5600 Fishers Lane,  
Rockville, MD 20857,  
301-594-2041.

SUPPLEMENTARY INFORMATION:

I. Background

On October 28, 1998, the U.S. District Court for the District of Maryland accepted Mr. Edmund J. Striefsky's plea of guilty to one count of distributing an adulterated drug into interstate commerce, a Federal felony offense under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)).

As a result of this conviction, FDA hand delivered to Mr. Striefsky on February 11, 2003, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Mr. Striefsky an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Mr. Striefsky was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Striefsky was provided 30 days to file

objections and request a hearing. Mr. Striefsky did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

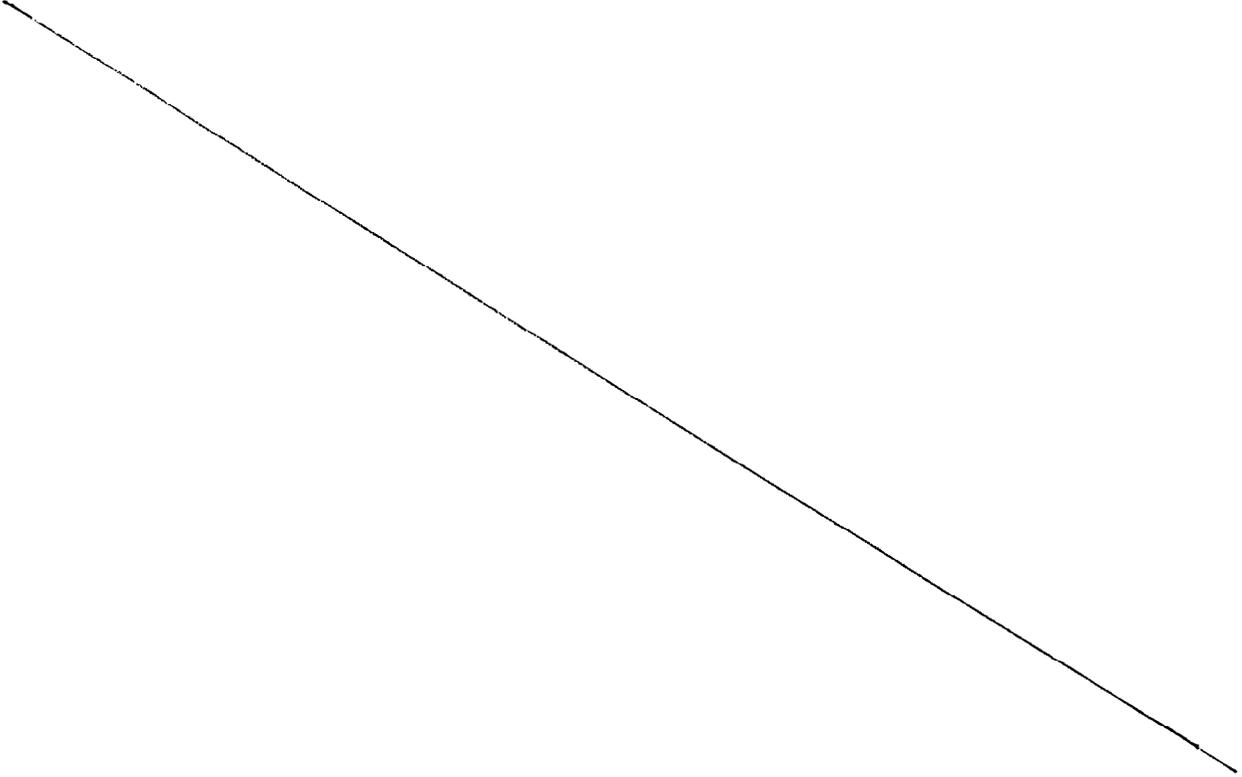
## II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.34), finds that Mr. Edmund J. Striefsky has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Mr. Edmund J. Striefsky is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 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) (see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Striefsky, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Striefsky, during his period of

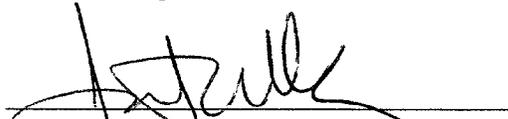
debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Striefsky during his period of debarment.

Any application by Mr. Striefsky for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 2000N-1427 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR



10.20(j). Publicly available submissions may be seen in  
the <sup>Director's Office</sup> Dockets Management Branch between 9 a.m. and 4 p.m.,  
Monday through Friday.

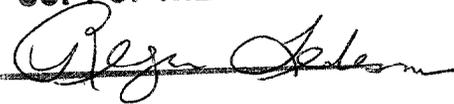
Dated: 9/4/03  
September 4, 2003.

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

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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**CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL**

  
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