

Sardesai 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. Suhas V. Sardesai 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. Sardesai, 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. Sardesai, 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. Sardesai during his period of debarment.

Any application by Mr. Sardesai for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 2000N-1428 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 4, 2003.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03-24655 Filed 9-29-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000N-1427]

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 debarred 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 September 30, 2003.

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, 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 4, 2003.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 03-24657 Filed 9-29-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

Name: Advisory Committee on Training in Primary Care Medicine and Dentistry.

Date and Time: October 23, 2003, 8:30 a.m.–4:30 p.m.; October 24, 2003, 8 a.m.–2 p.m.

Place: The Holiday Inn Select, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

Status: The meeting will be open to the public.

Purpose: The Advisory Committee provides advice and recommendations on a broad range of issues dealing with programs and activities authorized under section 747 of the Public Health Service Act as amended by The Health Professions Education Partnership Act of 1998, Public Law 105–392. At this meeting the Advisory Committee will begin work on its fourth report which will be submitted to Congress and the Secretary of the Department of Health and Human Services in November 2004. The fourth report focuses on the role of primary care in health care delivery in the future and the implications for training health professionals.

Agenda: The meeting on Thursday, October 23, will begin with welcoming and opening comments from the Chair of the Advisory Committee. A plenary session will follow in which Advisory Committee members will hear speakers address the topic of the future of primary care medicine and dentistry. The Advisory Committee will begin its work on the fourth report.

On Friday, October 24, the Advisory Committee will meet in plenary session to discuss training needs of health professionals in the future. Meeting in workgroups, the Advisory Committee will structure various portions of the fourth report. An opportunity will be provided for public comment.

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerilyn K. Glass, MD, PhD, Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Room 9A–21, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6326. The web address for information on the Advisory Committee is <http://bhpr.hrsa.gov/medicine-dentistry/actpcmd>.

Dated: September 23, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–24658 Filed 9–29–03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Public Meeting of the Airport and Seaport User Fee Advisory Committee

AGENCY: Customs and Border Protection, Department of Homeland Security.

ACTION: Notice of meeting.

SUMMARY: This document announces the date, time, and location for a public

meeting of the Airport and Seaport User Fee Advisory Committee and the agenda for consideration by the Committee. It also invites submission of written statements. In order to be considered for discussion at the meeting, a statement must be received by the Committee at least five days prior to the date of the meeting.

DATES: The 26th meeting of the Airport and Seaport User Fee Advisory Committee will be held on Wednesday, October 22, 2003, at 1 p.m., at the Office of Field Operations, Bureau of Customs and Border Protection, 5th Floor Bridge Conference Room, International Trade Center, 1300 Pennsylvania Avenue, NW., Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Cynthia Sargent, Office of Finance, (202) 927–0609; email:

cynthia.sargent@dhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Airport and Seaport User Fee Advisory Committee was created under the authority of 8 U.S.C. 1356(k) (section 286(k) of the Immigration and Nationality Act, as amended; see also the Federal Advisory Committee Act (5 U.S.C.A. App. § 2)) to meet periodically and advise the Attorney General on issues related to the performance of certain inspectional services performed by the Immigration and Naturalization Service (INS). Since the legacy INS inspection component has been merged with the U.S. Customs Service (along with other agencies) to form the Bureau of Customs and Border Protection (CBP), effective on March 1, 2003, the function of the Committee is now under CBP and the Committee now advises the Secretary of Homeland Security.

The Committee consists of representatives of the airline and other transportation industries that are subject to fees and charges authorized by law or proposed by the governing agency (either INS prior to March 1, 2003, or CBP afterward). Matters of consideration by the Committee include time periods during which inspectional services should be performed, number and deployment of inspectional officers, the level of fees, and the appropriateness of any proposed fee. The fees addressed by the Committee are immigration fees and should not be confused with COBRA fees authorized under 19 U.S.C. 58c.

Generally, the Committee focuses its attention on those subjects that most concern and benefit the travel industry, the traveling public, and CBP. One such subject is the fee charged for immigration inspectional services under 8 U.S.C. 1356(d) (section 286(d) of the

Immigration and Nationality Act, as amended). This fee applies to each passenger arriving at a port of entry in the United States, or to the preinspection of a passenger in a place outside the United States prior to arrival in the United States, aboard a commercial aircraft or vessel.

Public Meeting

In accordance with 8 U.S.C. 1356(k), CBP announces that the twenty-sixth meeting of the Airport and Seaport User Fee Advisory Committee will take place at 1 p.m. on October 22, 2003, at CBP Headquarters, Office of Field Operations, 5th Floor Bridge Conference Room, 1300 Pennsylvania Avenue, NW., Washington, DC 20229. The meeting is open to the public, and advance notice of attendance is requested to ensure adequate seating. Persons planning to attend should notify the contact person identified previously in this notice at least five days prior to the meeting. Any interested party may submit a written statement at any time before or after the meeting to the contact person for consideration by the Committee. Written statements received by the contact person at least five days prior to the meeting will be considered for discussion at the meeting.

Meeting Agenda

At this meeting, the Committee is expected to pursue the following agenda (which may be modified prior to the meeting):

1. Introduction of the Committee members;
2. Discussion of administrative issues;
3. Discussion of activities since last meeting;
4. Discussion of specific concerns and questions of Committee members;
5. Discussion of future traffic trends;
6. Discussion of relevant written statements timely submitted by the public in advance of the meeting (as above); and
7. Scheduling of next meeting.

Dated: September 26, 2003.

John E. Eichelberger,

Assistant Commissioner, Office of Finance.

[FR Doc. 03–24845 Filed 9–29–03; 8:45 am]

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