

the documents referenced in this AD from the Cessna Aircraft Company, Product Support, P.O. Box 7706, Wichita, Kansas 67277; telephone: (316) 517-5800; facsimile: (316) 942-9006. You may view these documents at FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106.

(g) *Does this AD action affect any existing AD actions?* This amendment supersedes AD 2000-23-01, Amendment 39-11971.

Issued in Kansas City, Missouri, on May 9, 2003.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA-162W]

#### **Schedules of Controlled Substances: Proposed Removal of Fenfluramine From the Controlled Substances Act; Withdrawal of Proposed Rule**

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Withdrawal of proposed rule.

**SUMMARY:** The Drug Enforcement Administration (DEA) is withdrawing a proposed rule that appeared in the **Federal Register** of May 6, 1997 (62 FR 24620) and is terminating the rulemaking. The proposed rule would have removed fenfluramine from schedule IV of the Controlled Substances Act. The drug's manufacturer has withdrawn its original petition that requested decontrol. DEA has determined that fenfluramine should remain in schedule IV due to the withdrawal of the petition, the removal of products containing the drug from the United States marketplace, and the public health and safety concerns expressed by the Department of Health and Human Services that arose after publication of the proposed rule.

**FOR FURTHER INFORMATION CONTACT:** Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307-7183.

**SUPPLEMENTARY INFORMATION:** In 1973, fenfluramine, its salts, isomers and salts of isomers were placed into schedule IV of the Controlled Substances Act (CSA), 21 CFR 1308.14(d). On March 18, 1991, Interneuron Pharmaceuticals, Inc., the manufacturer of a fenfluramine product (dexfenfluramine, brand name Redux),

petitioned DEA to decontrol fenfluramine. The fenfluramine product Redux, an anorectic indicated for the management of exogenous obesity, was approved by the Food and Drug Administration (FDA) of the Department of Health and Human Services (DHHS) for marketing in the United States in 1996. After receiving Interneuron's petition, and in accordance with the CSA requirements at 21 U.S.C. 811(b), DEA reviewed available data about fenfluramine. On June 3, 1996, the DHHS Assistant Secretary of Health submitted a recommendation to DEA that the substance be decontrolled. As a result of DEA's review and DHHS's recommendation, a notice of proposed rulemaking titled "Schedules of Controlled Substances: Proposed Removal of Fenfluramine From the Controlled Substances Act" was published on May 6, 1997 in the **Federal Register** (62 FR 24620). This notice of proposed rulemaking was in direct response to Interneuron's petition to decontrol fenfluramine. A sixty day comment period was provided during which four comments were received, two in favor of the proposed action and two against decontrol.

On July 8, 1997, two months after the proposed rulemaking was published, FDA issued a public health advisory regarding the use of fenfluramine, especially in conjunction with phentermine (commonly known as "fen-phen"), citing evidence of significant side effects associated with fenfluramine. FDA announced a voluntary withdrawal by the pharmaceutical manufacturers of fenfluramine (brand name Pondimin) and dexfenfluramine (brand name Redux) from United States markets on September 15, 1997. DHHS issued a final rule on March 8, 1999 listing drug products that were withdrawn or removed from the market because they were found to be unsafe or not effective, including fenfluramine hydrochloride. (64 FR 10944). This regulation is codified at 21 CFR 216.24.

In a February 27, 2003 letter addressed to DEA's Acting Administrator, John B. Brown III, Indevus Pharmaceuticals, Inc., formerly known as Interneuron Pharmaceuticals, Inc., wrote to withdraw its petition to decontrol fenfluramine because the company no longer markets fenfluramine products in the United States.

As a result of the recent withdrawal of the petition and the earlier removal of the drug from the United States marketplace by FDA due to health and safety concerns, DEA now has reason to reconsider its proposed rulemaking.

DEA no longer considers it appropriate to remove fenfluramine from schedule IV. The health and safety concerns that prompted the manufacturers' voluntary withdrawal of fenfluramine from the marketplace and DHHS's subsequent codification of this withdrawal, *see* 21 CFR 216.24, occurred after DEA's proposed rulemaking was published. Based on these events, DEA has determined that fenfluramine's current placement in schedule IV should not be altered. Accordingly, DEA withdraws the proposed rule published in the **Federal Register** on May 6, 1997 (62 FR 24620) and hereby terminates this rulemaking.

Dated: May 2, 2003.

**John B. Brown, III,**

*Acting Administrator.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[CGD05-03-023]

RIN 1625-AA00

#### **Safety and Security Zone; Cove Point Liquefied Natural Gas Terminal, Chesapeake Bay, MD**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking; notice of public meeting; reopening of comment period.

**SUMMARY:** On March 20, 2003, the U.S. Coast Guard Captain of the Port, Baltimore (COTP) published a notice of proposed rulemaking for revising a safety and security zone for the Cove Point Liquefied Natural Gas Terminal. In response to that notice, the COTP received requests for a public meeting to discuss the proposed rule. In this notice, the COTP is announcing a public meeting to receive comments regarding the proposed safety and security zone and is reopening the comment period for this rulemaking.

**DATES:** The meeting will be held Thursday, June 5, 2003, from 6 p.m. to 9 p.m. Comments and related material must reach the Coast Guard on or before June 12, 2003.

**ADDRESSES:** The meeting location is: The Holiday Inn, 155 Holiday Drive, Solomon's Island, Maryland. You may mail comments and related material to Commander, U.S. Coast Guard Activities, 2401 Hawkins Point Road,