Substances Import and Export Act shall be unlawful.

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking on the record after opportunity for a hearing. Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, Section 3(d)(1).

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this final rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. Modafinil is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marketed once it is placed into Schedule IV of the CAS. This final rule will allow these entities to have access to a new pharmaceutical product.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not

significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of

This rule is not a major rule as defined by section 804 of the Small **Business Regulatory Enforcement** Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreignbased companies in domestic and export markets.

. This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

## List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

## PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.14 is amended by redesignating the existing paragraphs (e)(7) through (e)(11) as (e)(8) through (e)(12) and by adding a new paragraph (e)(7) to read as follows: § 1308.14 Schedule IV.

\* (e) \* \* \*

1680 (7) Modafinil

vessel, ongoing oil pollution response

operations and the exposed location

Dated: January 20, 1999.

### Donnie R. Marshall,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 99-1791 Filed 1-26-99; 8:45 am]

BILLING CODE 4410-09-M

salvage operations. Entry into this zone is prohibited unless authorized by the Captain of the Port (COTP), Providence **EFFECTIVE DATES:** This rule is effective

from 12 o'clock, noon, on Tuesday, January 12, 1999 until 12 o'clock, midnight, on Friday, February 12, 1999. FOR FURTHER INFORMATION CONTACT: CWO Payne, Waterways Management, Coast Guard Marine Safety Office, Providence RI, at (401) 435-2300.

SUPPLEMENTARY INFORMATION:

## **Regulatory History**

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking (NPRM) was not published for this regulation and good cause exists for making it effective less then 30 days after Federal Register publication. Due to the date that conclusive information for this event was received there was insufficient time to draft and publish an NPRM. Any delay encountered in this regulation's effective date would be contrary to public interest since immediate action is needed to close a portion of the entrance to Buzzards Bay to protect the maritime public from the hazards associated with

the sunken vessel, on going oil pollution response and the exposed location salvage operation.

### **Background and Purpose**

This regulation establishes a safety zone in all the waters within a five hundred (500) yard radius of the site of the sunken fishing vessel CAPE FEAR (O.N. D655734) in the entrance to Buzzards Bay in approximate position 41–23N and 71–01W. The safety zone is needed to protect vessels from the hazards associated with the sunken vessel, on going pollution response and the exposed location salvage operation. No vessel may enter the safety zone without permission of the Captain of the Port, Providence, RI.

## **Regulatory Evaluation**

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT)(44 FR 11040; February 26, 1979).

## DEPARTMENT OF TRANSPORTATION

# **Coast Guard**

33 CFR Part 165

[CGD01 99-002]

RIN 2115-AA97

Safety Zone: Sunken Fishing Vessel Cape Fear, Buzzards Bay Entrance

AGENCY: Coast Guard, DOT. **ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a safety zone within a five hundred (500) yard radius of the site of the sunken fishing vessel CAPE FEAR (O.N. D655734) in the entrance to Buzzards Bay at approximate position 41–23 North and 71–01 West. This safety zone is needed to protect the maritime community from possible hazards associated with the sunken

The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. Costs to the shipping industry from these regulations if any, will be minor and have no significant adverse financial effect on vessel operators. In addition, due to the limited number of vessels affected, the Coast Guard expects the economic impact of this regulation to be so minimal that a Regulatory Evaluation is unnecessary.

## **Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. *et seq.*), the Coast Guard must consider whether this proposal will have a significant economic impact on a substantial number of small entities. "Small entities" may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000.

For the reasons addressed in the Regulatory Evaluation above, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

## **Collection of Information**

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

#### **Federalism**

The Coast Guard has analyzed this action in accordance with the principles and criteria contained in Executive Order 12612, and has determined that these regulations do not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### **Environment**

The Coast Guard has considered the environmental impact of these regulations and concluded that under Figure 2–1, paragraph 34(g) of Commandant Instruction M16475.1C, this final rule is categorically excluded from further environmental documentation.

## List of Subjects in 33 CFR Part 165

Habors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

### Regulation

For the reasons set out in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

### PART 165—[AMENDED]

1. The authority citation for Part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5; 49 CFR 1.46.

2. Add temporary section 165.T01–002 to read as follows:

# § 165.T01-002 Safety Zone: Sunken Fishing Vessel CAPE FEAR, Buzzards Bay Entrance.

- (a) *Location.* The following area has been declared a safety zone: All waters within a five hundred (500) yard radius of the site of the sunken fishing vessel CAPE FEAR (O.N. D655734), in the entrance to Buzzards Bay in approximate position 41–23 North and 71–01 West.
- (b) Effective date: This section is effective from 12 noon, on Tuesday, January 12, 1999 until 12 midnight, on Friday 12, 1999.
  - (c) Regulations.
- (1) In accordance with the general regulations in § 165.23 of this part, entry into or movement within this zone is prohibited unless authorized by the COTP Providence.
- (2) All persons and vessels shall comply with the instructions of the COTP or the designated on-scene U.S. Coast Guard patrol personnel. U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast guard.
- (3) The general regulations covering safety zones in section 165.23 of this part apply.

Dated: January 12. 1999.

## Peter A. Popko,

Captain, U.S. Coast Guard, Captain of the Port.

[FR Doc. 99–1881 Filed 1–26–99; 8:45 am]

#### **DEPARTMENT OF TRANSPORTATION**

**Coast Guard** 

33 CFR Part 165

[CGD01-98-184]

RIN 2115-AA97

Safety Zone: Swift Creek Channel, Freeport, NY

**AGENCY:** Coast Guard, DOT. **ACTION:** Temporary final rule.

summary: The Coast Guard is establishing a temporary safety zone that includes all waters within 200 yards of the Loop Parkway Bridge which spans Swift Creek channel, Freeport, NY. The safety zone is needed to facilitate the construction of the new loop parkway bridge. Entry into this safety zone is prohibited unless authorized by the Captain of the Port, Long Island Sound, New Haven, CT.

**EFFECTIVE DATE:** This regulation is effective on January 1, 1999, from 8 a.m. until March 1, 1999.

ADDRESSES: Documents relating to this temporary final rule are available for inspection and copying at U.S. Coast Guard Group/MSO Long Island Sound, 120 Woodward Ave, New Haven, CT 06512. Normal office hours are between 8 a.m. and 4 p.m., Monday through Friday, except holidays.

#### FOR FURTHER INFORMATION CONTACT:

Lieutenant Commander T.J. Walker, Chief of Port Operations, Captain of the Port, Long Island Sound at (203) 468– 4444.

#### SUPPLEMENTARY INFORMATION:

## **Regulatory History**

A notice of proposed rulemaking (NPRM) was not published for this regulation. In keeping with the requirements of 5 U.S.C. 553(d)(3), the Coast Guard also finds that good cause exists for making this regulation effective less than 30 days after publication in the **Federal Register.** Due to construction requirements, this office had insufficient time to publish a proposed rule in advance of the event. Publishing a NPRM and delaying the effective date would effectively suspend work on the new bridge, which would be contrary to the public interest.

## **Background and Purpose**

A safety zone preventing vessels from transiting the Swift Creek channel beneath the Loop Parkway bridge because of construction of a new bridge has been in effect since September 8, 1998 and will expire on December 31, 1998. The safety zone has been needed to facilitate the building of the center of the bridge and to protect construction personnel and the maritime community. Construction of the new bridge has not been completed and therefore and additional safety zone preventing vessels from transiting the Swift Creek channel is needed. Entry into or movement within this zone is prohibited unless authorized by the Captain of the Port.