

(3) Where a requester has previously failed to pay a properly charged FOIA fee to TVA or another agency within 30 days of the date of billing, TVA may require the requester to pay the full amount due, plus any applicable interest, and to make an advance payment of the full amount of any anticipated fee, before TVA begins to process a new request or continues to process a pending request from that requester.

(4) In cases in which TVA requires advance payment or payment due under paragraph (i) (2) or (3) of this section, the request shall not be considered received and further work will not be done on it until the required payment is received.

(j) *Other fees for TVA published materials.* The fee schedule of this section does not apply to fees charged by TVA for documents, including maps or reports and the like, which TVA sells to the public at established prices. Where records responsive to requests are maintained for distribution and sale by TVA at established prices. TVA will inform requesters of the steps for obtaining records from those sources so that they may do so most economically.

(k) *Waiver or reduction of fees.* (1) Records responsive to a request will be furnished without charge or at a charge reduced below that established under paragraph (c) of this section where TVA determines, based on all available information, that the requester has documented that:

(i) Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, and

(ii) Disclosure of the information is not primarily in the commercial interest of the requester.

(2) To determine whether the first fee waiver requirement is met, TVA will consider the following factors:

(i) The subject of the request: Whether the subject of the requested records concerns "the operations or activities of the government." The subject of the requested records must concern identifiable operations or activities of the federal government, with a connection that is direct and clear, not remote or attenuated.

(ii) The informative value of the information to be disclosed: Whether the disclosure is "likely to contribute" to an understanding of government operations or activities. The disclosable portions of the requested records must be meaningfully informative about government operations or activities in order to be "likely to contribute" to an

increased public understanding of those operations or activities. The disclosure of information that already is in the public domain, in either a duplicative or a substantially identical form, would not be as likely to contribute to such understanding where nothing new would be added to the public's understanding.

(iii) The contribution to an understanding of the subject by the public likely to result from disclosure: Whether disclosure of the requested information will contribute to "public understanding." The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area and ability and intention to effectively convey information to the public shall be considered. It shall be presumed that a representative of the news media will satisfy this consideration.

(iv) The significance of the contribution to public understanding: Whether the disclosure is likely to contribute "significantly" to public understanding of government operations or activities. The public's understanding of the subject in question, as compared to the level of public understanding existing prior to the disclosure, must be enhanced by the disclosure to a significant extent. TVA shall not make value judgments about whether information that would contribute significantly to public understanding of the operations or activities of the government is "important" enough to be made public.

(3) To determine whether the second fee waiver requirement is met, TVA will consider the following factors:

(i) The existence and magnitude of a commercial interest: Whether the requester has a commercial interest that would be furthered by the requested disclosure. TVA shall consider any commercial interest of the requester (with reference to the definition of "commercial use" in paragraph (b) (1) of this section), or of any person on whose behalf the requester may be acting, that would be furthered by the requested disclosure. Requesters shall be given an opportunity in the administrative process to provide explanatory information regarding this consideration.

(ii) The primary interest in disclosure. Whether any identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is "primarily in the commercial interest of the requester." A fee waiver or

reduction is justified where the public interest standard is satisfied and that public interest is greater in magnitude than that of any identified commercial interest in disclosure. TVA ordinarily shall presume that where a news media requester has satisfied the public interest standard, the public interest will be the interest primarily served by disclosure to that requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return shall not be presumed to primarily serve the public interest.

(4) Where only some of the requested records satisfy the requirements for a waiver of fees, a waiver shall be granted for those records.

(5) Requests for the waiver or reduction of fees should address the factors listed in paragraphs (k) (2) and (3) of this section, insofar as they apply to each request. TVA will exercise their discretion to consider the cost-effectiveness of their investment of administrative resources in this decisionmaking process, however, in deciding to grant waivers or reductions of fees.

William S. Moore,

Senior Manager, Administrative Services.

[FR Doc. 99-1870 Filed 1-26-99; 8:45 am]

BILLING CODE 8120-08-P

DEPARTMENT OF JUSTICE

21 CFR Part 1308

[DEA-17F]

Schedules of Controlled Substances: Placement of Modafinil Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance, modafinil, including its salts, isomers and salts of isomers, into Schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, importation and exportation of modafinil and products containing modafinil.

EFFECTIVE DATE: January 27, 1999.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration,

Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Modafinil is a central nervous system (CNS) stimulant that produces many of the same pharmacological effects and adverse reactions as classic psychomotor stimulants, but at higher doses. Modafinil will be marketed as a prescription drug product for the treatment of excessive daytime sleepiness associated with narcolepsy under the trade name Provigil®.

On December 22, 1997, the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Acting Deputy Administrator of DEA a letter recommending that modafinil, and its salts, be placed into Schedule IV of the CSA (21 U.S.C. 801 *et seq.*). Enclosed with the December 22, 1997 letter was a document prepared by the Food and Drug Administration (FDA) entitled "Basis for the Recommendation for Control of Modafinil in Schedule IV of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

Subsequent correspondent from the FDA's Associate Commissioner for Health Affairs dated February 24, 1998, confirmed that the FDA had determined that the New Drug Application (NDA) for modafinil was "approvable" and had issued an approvable letter to the NDA sponsor on December 29, 1997. According to the February 24, 1998 letter from the FDA, "upon full approval of the NDA, modafinil will have a currently accepted medical use in treatment in the United States."

After a review of the available data, including the DHHS recommendation, the Acting Deputy Administrator of the DEA, in an April 14, 1998 **Federal Register** notice (63 FR 18170), proposed placement of modafinil into Schedule IV of the CSA, if and when the modafinil NDA is approved by the FDA. The notice provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing in writing to be received by the DEA on or before May 14, 1998.

The DEA received one comment regarding the proposal. The comment was received from Cephalon, Inc., the company sponsoring the modafinil NDA. The comment did not object to the placement of modafinil in Schedule IV, but requested clarification of some of the descriptions of the pharmacological effects of modafinil. Cephalon, Inc. commented that modafinil did not produce significant dopaminergic activity nor did it produce classic

dopaminergic-like pharmacological effects. Cephalon also stated that the time to peak pharmacological activity of modafinil is one to three hours and the effects last six to eight hours after oral administration. It did not characterize such pharmacodynamic effects of modafinil as "quick onset and short duration of action," as they were described in the **Federal Register** proposal.

The DEA's review of the DHHS scheduling recommendation and review document and the available scientific literature indicates that the precise biochemical mechanism of action of modafinil is not clearly defined. Data indicate that modafinil does not act directly on any single neurotransmitter system, but appears to act indirectly on dopaminergic, serotonergic, and GABA systems. Although its mechanism of action may not be mediated primarily through the dopaminergic system, the behavioral and pharmacological effects and adverse reactions produced by modafinil are similar to those of other psychomotor or stimulants which produce significant dopaminergic activity. The data reviewed by the DHHS and the DEA show that modafinil is well-absorbed after oral administration. Peak plasma concentration for modafinil occurs at one to four hours. Elimination half-life was nine to fourteen hours after oral administration of 200 to 400 mg of modafinil. These pharmacodynamic actions of modafinil were characterized at "fast onset and short duration" by the DHHS. Thus, the modafinil data presented in the **Federal Register** proposal and the comments by Cephalon regarding these statements are not substantive scientific discrepancies, but are differences in describing the same data.

On December 30, 1998, the FDA notified the DEA that the modafinil NDA was approved by the FDA on December 24, 1998. Relying on the scientific and medical evaluation and the recommendation of the DHHS Acting Assistant Secretary for Health received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), communication with the FDA Associate Commissioner for Health and the independent review of the DEA, the Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Based on information now available, modafinil has a low potential for abuse relative to the drugs or other substances in Schedule III;

(2) Modafinil has a currently accepted medical use in treatment in the United States; and

(3) Abuse of modafinil may lead to limited physical dependence and psychological dependence relative to the drugs or other substances in Schedule III.

Based on these findings, the Deputy Administrator of the DEA concludes that modafinil, including its salts, isomers and salts of isomers, warrants control in Schedule IV of the CSA. In order to make modafinil pharmaceutical products available for medical use as soon as possible, the Schedule IV controls of modafinil will be effective January 27, 1999. In the event that the regulations impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the Schedule IV regulations regarding modafinil. The applicable regulations are as follows:

1. **Registration.** Any person who manufactures, distributes, dispenses, imports or exports modafinil or who engages in research or conducts instructional activities with modafinil, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations.

2. **Security.** Modafinil must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75 (b) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. **Labeling and Packaging.** All labels on commercial containers of, and all labeling of, modafinil which is distributed shall comply with the requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

4. **Inventory.** Registrants possessing modafinil are required to take inventories pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations.

5. **Records.** All registrants must keep records pursuant to §§ 1304.03, 1304.04 and 1304.21–1304.23 of Title 21 of the Code of Federal Regulations.

6. **Prescriptions.** All prescriptions for modafinil are to be issued pursuant to §§ 1306.03–1306.06 and 1306.21–1306.26 of Title 21 of the Code of Federal Regulations.

7. **Importation and Exportation.** All importation and exportation of modafinil shall be in compliance with Part 1312 of Title 21 of the Federal Code of Regulations.

8. **Criminal Liability.** Any activity with modafinil not authorized by, or in violation of, the CAS or the Controlled

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 1995.

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 foreign-based 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.

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(7) Modafinil 1680

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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

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

vessel, ongoing oil pollution response operations and the exposed location salvage operations. Entry into this zone is prohibited unless authorized by the Captain of the Port (COTP), Providence RI.

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 than 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).