

fastener holes in the stiffeners and rib posts between FSS 570 and FSS 684.

(4) Perform an ultrasonic inspection to detect cracked or broken fasteners in the fasteners attaching only the web to the chords, in the top two and bottom two rows of the fasteners attaching the web to the stiffeners, and in the top two and bottom two rows of the fasteners attaching the web to the rib posts. This inspection area is located between FSS 570 and FSS 684.

(d) For airplanes identified as Configuration B in Boeing Alert Service Bulletin 747-57A2266, Revision 5, dated August 3, 1995: Within 18 months following accomplishment of the terminating action (fastener replacement) specified in Boeing Service Bulletin 747-57A2266, dated June 6, 1991, Revision 1, dated May 21, 1992, or Revision 2, dated June 10, 1993' or within 12 months after the effective date of this AD' or within 2,000 flight cycles after the immediately preceding inspection accomplished in accordance with paragraph (a) or (b) of this AD' whichever occurs latest; accomplish the inspections specified in paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) of this AD in accordance with Figure 4 of Boeing Alert Service Bulletin 747-57A2266, Revision 5, dated August 3, 1995. Repeat these inspections thereafter at intervals not to exceed 2,000 flight cycles. Accomplishment of these inspections terminates the inspections required by paragraphs (a) and (b) of this AD.

(1) Perform a detailed visual inspection to detect damage and fuel leaks in the general area of the web of the wing front spar between FSS 570 and FSS 636 and between FSS 675 and FSS 684.

(2) Perform an eddy current inspection to detect cracks along the web near the edges of the vertical flange of the upper and lower chords of the wing front spar between FSS 570 and FSS 636 and between FSS 675 and FSS 684.

(3) Perform an ultrasonic inspection to detect cracks in the web around the first two fastener holes in the stiffeners and rib posts between FSS 570 and FSS 636 and between FSS 675 and FSS 684.

(4) Perform an ultrasonic inspection to detect cracked or broken fasteners in the fasteners attaching only the web to the chords, in the top two and bottom two rows of the fasteners attaching the web to the stiffeners, and in the top two and bottom two rows of the fasteners attaching the web to the rib posts. This inspection area is located between FSS 570 and FSS 636 and between FSS 675 and FSS 684.

(e) If any discrepancy (i.e., cracking, fuel leakage, broken fasteners) is detected during any inspection required by this AD, prior to further flight, repair in accordance with paragraphs E. and H. (as applicable) of the Accomplishment Instructions of Boeing Service Bulletin 747-57A2266, Revision 3, dated March 31, 1994; Boeing Service Bulletin 747-57A2266, Revision 4, dated November 3, 1994; or Boeing Alert Service Bulletin 747-57A2266, Revision 5, dated August 3, 1995. Thereafter, continue to inspect the remaining fasteners in accordance with paragraph (c) or (d) of this AD, as applicable, until the terminating action

specified in paragraph (f) of this AD is accomplished. If any crack is found that cannot be removed by oversizing the fastener hole, prior to further flight, repair it in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate.

(f) Replacement of the fasteners in the web-to-chords and of the fasteners in the web-to-stiffeners and web-to-rib posts, as specified in Boeing Service Bulletin 747-57A2266, Revision 3, dated March 31, 1994; Revision 4, dated November 3, 1994, or Revision 5 dated August 3, 1995; with oversized fasteners on each wing spar in accordance with the service bulletin constitutes terminating action for the repetitive inspections required by paragraphs (a), (b), (c), (d), and (e) of this AD.

(g) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(h) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on April 7, 1998.

**Darrell M. Pederson,**

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

[FR Doc. 98-9752 Filed 4-13-98; 8:45 am]

BILLING CODE 4910-13-U

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Part 1308**

[DEA-174P]

**Schedules of Controlled Substances: Proposed Placement of Modafinil Into Schedule IV**

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This proposed rule is issued by the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) to place the substance modafinil, including its salts, isomers and salts of isomers, into Schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Acting

Assistant Secretary for Health of the Department of Health and Human Services (DHHS) that modafinil be added to Schedule IV and on an evaluation of the relevant data by the DEA. The scheduling of modafinil in Schedule IV will not be finalized until the New Drug Application (NDA) for modafinil is approved by the Food and Drug Administration (FDA). If finalized, this action will impose the regulatory controls and criminal sanctions of Schedule IV on those who handle modafinil and products containing modafinil.

**DATES:** Comments, objections and requests for a hearing must be received on or before May 14, 1998.

**ADDRESSES:** Comments, objections and requests for a hearing should be submitted in quintuplicate to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537; Attention: DEA Federal Register Representative/CCR.

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

**SUPPLEMENTARY INFORMATION:** Modafinil is a central nervous system (CNS) stimulant that is being considered for marketing approval by the FDA, under the trade name Provigil®. If approved, modafinil will be marketed as a prescription drug product for the treatment of excessive daytime sleepiness associated with narcolepsy. Modafinil produces many of the same pharmacological effects and adverse reactions as, but is up to 50 to 100 times less potent than, classic psychomotor stimulants, such as amphetamine, methamphetamine and methylphenidate, all in Schedule II of the CSA.

Modafinil is a racemic mixture of *levo*- and *dextro*-isomers. Modafinil is structurally different from other CNS stimulants, such as cocaine, amphetamine, methamphetamine and methylphenidate. Modafinil binds at dopamine receptors and is active at central dopamine binding sites. It has a quick onset and short duration of action. Modafinil is reinforcing in animals, and produces euphoria, alterations in mood, perception, thinking and subjective effects typical of other classic Schedule II psychomotor stimulants. The *levo*-isomer, *dextro*-isomer and racemate are equipotent and produce similar behavioral effects.

Despite its classic CNS stimulant-like pharmacological profile, modafinil appears to have chemical properties that may limit its abuse (i.e., not water

soluble, decomposes in heat). In addition, relative potency differences between modafinil and other CNS stimulants in Schedule II are significant. These properties reduce the likelihood that modafinil could be abused by the parenteral, intranasal or inhalation route, as are cocaine, methylphenidate, and amphetamine. Thus, its abuse potential appears to be lower than that of Schedule II stimulants and similar to that of Schedule IV stimulants. The DEA is unaware of any reports of modafinil abuse.

On December 22, 1997, the Acting Assistant Secretary for Health sent the Acting Deputy Administrator of DEA a letter recommending that modafinil, and its salts, be placed in 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 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 correspondence from the FDA's Associate Commissioner for Health Affairs dated February 24, 1998, confirmed that FDA continues to evaluate the pending New Drug Application for modafinil. The FDA has determined that the NDA is "approvable" and has issued an approvable letter to the NDA sponsor on December 29, 1997. According to the February 24, 1998 letter from FDA, "upon full approval of the NDA, modafinil will have a currently accepted medical use in the United States."

The factors considered by the Acting Assistant Secretary for Health and the DEA with respect to modafinil were:

- (1) Its actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effect;
- (3) The state of current scientific knowledge regarding the drug;
- (4) Its history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) What, if any, risk there is to the public health;
- (7) Its psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Relying on the scientific and medical evaluation, the recommendation of the Acting Assistant Secretary for Health, the letter from the FDA Associate

Commissioner for Health received in accordance with section 201(b) of the Act [21 U.S.C. 811(b)], and the independent review of the DEA, the Acting 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)], find 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 will, upon approval of a NDA by the FDA, have a currently accepted medical use in treatment in the United States; and

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

Based on these findings, the Acting Deputy Administrator of the DEA concludes that modafinil, including its salts, isomers, and salts of isomers, warrant control in Schedule IV of the CSA, if and when the modafinil NDA is approved by the FDA.

Interested persons are invited to submit their comments, objections or requests for a hearing, in writing, with regard to this proposal. Requests for a hearing should state, with particularity, the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the Acting Deputy Administrator, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative/CCR. In the event that comments, objections, or requests for a hearing raise one or more issues which the Acting Deputy Administrator finds warrants a hearing, the Acting Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing.

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 Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this proposed rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. Modafinil products will be prescription drugs used to treat narcolepsy. Handlers

of modafinil also handle other controlled substances used to treat narcolepsy which are already subject to the regulatory requirements of the CSA.

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 the 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, if finalized, will 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 Acting Deputy Administrator hereby proposes that 21 CFR part 1308 be amended 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 proposed to be 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) \* \* \*

(7) Modafinil .....1680

\* \* \* \* \*

Dated: April 6, 1998.

**Donnie R. Marshall,**

*Acting Deputy Administrator, Drug Enforcement Administration.*

[FR Doc. 98-9824 Filed 4-13-98; 8:45 am]

BILLING CODE 4410-09-M

**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation and Enforcement****30 CFR Part 924**

[SPATS No. MS-014-FOR]

**Mississippi Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

**ACTION:** Proposed rule; public comment period and opportunity for public hearing.

**SUMMARY:** OSM is announcing receipt of a proposed amendment to the Mississippi regulatory program (hereafter the "Mississippi program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to the Mississippi Surface Coal Mining and Reclamation Law pertaining to the small operator assistance program, variances from performance standards, enforcement, and administrative and judicial review proceedings. The amendment is intended to revise the Mississippi program to be consistent with SMCRA.

This document sets forth the times and locations that the Mississippi program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding the public hearings, if one is requested.

**DATES:** Written comments must be received by 4:00 p.m., c.d.t., May 14, 1998. If requested, a public hearing on the proposed amendment will be held on May 11, 1998. Requests to speak at the hearing must be received by 4:00 p.m., c.d.t. on April 29, 1998.

**ADDRESSES:** Written comments and requests to speak at the hearing should be mailed or hand delivered to Arthur W. Abbs, Director, Birmingham Field Office, at the address listed below.

Copies of the Mississippi program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Birmingham Field Office.

Arthur W. Abbs, Director, Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209, Telephone: (205) 290-7282.

Department of Environmental Quality, Office of Geology, 2380 Highway 80 West, P.O. Box 20307, Jackson, Mississippi 39289-1307, Telephone: (601) 961-5500.

**FOR FURTHER INFORMATION CONTACT:** Arthur W. Abbs, Director, Birmingham Field Office, Telephone: (205) 290-7282.

**SUPPLEMENTARY INFORMATION:****I. Background on the Mississippi Program**

On September 4, 1980, the Secretary of the Interior conditionally approved the Mississippi program. Background information on the Mississippi program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the September 4, 1980, **Federal Register** (45 FR 48520). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 924.10, 924.12, and 924.16.

**II. Description of the Proposed Amendment**

By letter dated March 26, 1998 (Administrative Record No. MS-0354), Mississippi submitted Senate Bill 3116 as a proposed amendment to its program pursuant to SMCRA. Mississippi submitted the proposed amendment in response to the required program amendments codified at 30 CFR 924.16 (b), (c), and (d). The Mississippi Legislature amended the Mississippi Surface Coal Mining and Reclamation Law at section 53-9-26 to clarify an applicant's eligibility for the small operator assistance program; section 53-9-45 to provide that specified variances for Reclamation performance standards apply to steep-slope mining; section 53-9-69 to require that a notice of violation shall be issued when a violation which does not pose an immediate threat is detected and to authorize the assessment of costs and expenses to certain persons participating in a

judicial review or an administrative review proceeding under certain circumstances; and section 53-9-77 to clarify that the availability of judicial review under this section shall not limit civil litigation rights. A discussion of the amendments to each section is presented below.

1. *§ 53-9-26, Small Operator Assistance Program.* Mississippi proposes to change the word "operation" to the word "operator" in the phrase "at all locations of a surface coal mining operation."

2. *§ 53-9-45, Variances From Performance Standards.* At section 53-9-45(4)(b), Mississippi proposes to remove the reference to subsection (2) in the phrase "a variance from the requirement to restore to approximate original contour set forth in subsection (2) or (3) of this section."

**3. § 53-9-69, Enforcement and Administrative and Judicial Review Proceedings**

a. At section 53-9-69(1)(c)(i), Mississippi proposes to change the word "may" to the word "shall" in the phrase "the commission, executive director or the executive director's authorized representative may issue an order to the permittee or agent of the permittee."

b. Mississippi proposes to add the following new provision at section 53-9-69(4):

(4) When an order is issued under this section, or as a result of any administrative proceeding under this chapter, at the request of any person, a sum equal to the aggregate amount of all costs and expenses, including attorney's fees, as determined by the commission to have been reasonably incurred by that person for or in conjunction with that person's participation in the proceedings, including any judicial review of agency actions, may be assessed against either party as the court, resulting from judicial review, or the commission, resulting from administrative proceedings deems proper.

**4. § 53-9-77, Formal Hearings.**

Mississippi proposes to add the following new provisions at section 53-9-77(5):

(5) Except as provided in Section 53-9-67, the availability of judicial review under this section shall not limit any rights established under Section 53-9-67.

**III. Public Comment Procedures**

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Mississippi program.