

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

**Airbus Industrie:** Docket 98–NM–08–AD.

**Applicability:** All Model A320 series airplanes, certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (h) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

**Compliance:** Required as indicated, unless accomplished previously.

To detect and correct fatigue cracking of the fuselage, which could result in reduced structural integrity of the airplane, accomplish the following:

(a) For airplanes on which Airbus Modification 21202 (reference Airbus Service Bulletin A320–53–1033, Revision 3, dated July 4, 1994) has not been accomplished: Prior to the accumulation of 30,000 total flight cycles, or within 6 months after the effective date of this AD, whichever occurs later, perform an ultrasonic inspection to detect cracking in the bottom panels of the keel beam (both left and right), in the area of the frame 46 and stringer 37 intersection at the pressure bulkhead, in accordance with Airbus Service Bulletin A320–53–1034, dated March 30, 1992. Thereafter, repeat the ultrasonic inspection at intervals not to exceed 6,000 flight cycles. If any crack is found, prior to further flight, repair in accordance with the service bulletin, except as provided by paragraph (g) of this AD.

(b) Accomplishment of Airbus Modification 21202 in accordance with Airbus Service Bulletin A320–53–1033, Revision 3, dated July 4, 1994, constitutes terminating action for the repetitive inspection requirement of paragraph (a) of this AD.

(c) For airplanes on which Airbus Modification 21346 (reference Airbus Service Bulletin A320–53–1031, dated December 9, 1994) has not been accomplished prior to the accumulation of 20,000 total flight cycles: Prior to the accumulation of 30,000 total flight cycles, or within 6 months after the effective date of this AD, whichever occurs later, perform a visual inspection to detect cracking on the outboard flanges around the fastener holes of frames 38 to 41, between stringers 12 and 21, in accordance with Airbus Service Bulletin A320–53–1032, Revision 1, dated January 15, 1998. Thereafter, repeat the visual inspection at intervals not to exceed 6,000 flight cycles. If any crack is found, prior to further flight,

repair in accordance with the service bulletin, except as provided by paragraph (g) of this AD. Accomplishment of a repair in accordance with the service bulletin terminates the repetitive inspection requirements for the area repaired.

(d) Accomplishment of Airbus Modification 21346 in accordance with Airbus Service Bulletin A320–53–1031, dated December 9, 1994, prior to the accumulation of 20,000 total flight cycles constitutes terminating action for the repetitive inspection requirement of paragraph (c) of this AD.

(e) For airplanes on which Airbus Modification 21905 (reference Airbus Service Bulletin A320–53–1056, Revision 02, dated February 16, 1998) has not been accomplished: Prior to the accumulation of 20,000 total flight cycles, or within 6 months after the effective date of this AD, whichever occurs later, perform a visual or eddy current inspection to detect cracking in the upper rivet row of the longitudinal lap joint, in accordance with Airbus Service Bulletin A320–53–1057, Revision 2, dated July 5, 1996.

(1) Thereafter, repeat the inspection at one of the following intervals:

(i) If the immediately preceding inspection was conducted using visual techniques, conduct the next inspection within 4,000 flight cycles.

(ii) If the immediately preceding inspection was conducted using eddy current techniques, conduct the next inspection within 12,000 flight cycles.

(2) If any crack is found, prior to further flight, repair in accordance with the service bulletin, except as provided by paragraph (g) of this AD. Accomplishment of a repair in accordance with the service bulletin terminates the repetitive inspection requirements for the area repaired.

(f) Accomplishment of Airbus Modification 21905 in accordance with Airbus Service Bulletin A320–53–1056, Revision 02, dated February 16, 1998, prior to the accumulation of 20,000 total flight cycles constitutes terminating action for the repetitive inspection requirements specified in paragraph (e)(1) of this AD.

(g) If any crack is found during any inspection required by paragraph (a), (c), or (e) of this AD, and the applicable service bulletin specifies to contact Airbus for appropriate action: Prior to further flight, repair in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate.

(h) 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, International Branch, ANM–116. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(i) 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.

**Note 3:** The subject of this AD is addressed in French airworthiness directives 97–314–108(B), 97–313–107(B), and 97–312–106(B), all dated October 22, 1997.

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

**Darrell M. Pederson,**

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

[FR Doc. 98–9753 Filed 4–13–98; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 97–NM–82–AD]

RIN 2120–AA64

#### Airworthiness Directives; Boeing Model 747–100 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This document proposes the superseding of an existing airworthiness directive (AD), applicable to certain Boeing Model 747–100 series airplanes, that currently requires repetitive inspections to detect cracking of the wing front spar web above engine numbers 2 and 3, and to detect cracked or broken fasteners in the web; and repair, if necessary. That AD also provides an optional terminating action for the repetitive inspections. This proposal would require various improved inspections. This proposal is prompted by a report indicating that the existing inspections do not adequately detect vertical cracks. The actions specified by the proposed AD are intended to prevent fuel leakage onto an engine and a resultant fire due to cracked or broken fasteners in the wing front spar.

**DATES:** Comments must be received by May 29, 1998.

**ADDRESSES:** Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 97–NM–82–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

**FOR FURTHER INFORMATION CONTACT:** Tamara L. Anderson, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2771; fax (425) 227-1181.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 97-NM-82-AD." The postcard will be date stamped and returned to the commenter.

**Availability of NPRMs**

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-114, Attention: Rules Docket No. 97-NM-82-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

**Discussion**

On January 24, 1995, the FAA issued AD 95-02-15, amendment 39-9134 (60 FR 9613, February 21, 1995), applicable to certain Boeing Model 747-100 series airplanes, to require repetitive

inspections to detect cracking of the wing front spar web above engine numbers 2 and 3, and to detect cracked or broken fasteners in the web; and repair, if necessary. That AD also provides for an optional terminating action for the repetitive inspections. That action was prompted by reports of broken fasteners and cracking of the web common to the upper and lower chords. The requirements of that AD are intended to prevent fuel leakage onto an engine and a resultant fire due to cracking or broken fasteners in the wing front spar.

**Actions Since Issuance of Previous Rule**

Since the issuance of that AD, the FAA has reviewed and approved Revision 5 of Boeing Alert Service Bulletin 747-57A2266, dated August 3, 1995. The revised alert service bulletin describes, among other things, the following various improved inspection procedures:

1. Repetitive eddy current inspections 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 front spar station (FSS) 570 and FSS 684. Certain inspection procedures specified in Revisions 3 and 4 of the alert service bulletin (which were referenced in AD 95-02-15 as the appropriate sources of service information for accomplishment of the inspections) do not adequately detect vertical cracks. Accomplishment of this new eddy current inspection will ensure that vertical cracks on the forward side of the web extending from behind the chord are detected.

2. Repetitive ultrasonic inspections to detect cracks in the web around the first two fastener holes in the stiffeners and rib posts between FSS 570 and FSS 684. Accomplishment of this new inspection will ensure that vertical cracks of the web under the stiffeners that start from the fastener holes are detected.

The remaining inspection procedures and follow-on actions specified in Revision 5 of the alert service bulletin are essentially identical to those described in Revisions 3 and 4.

**Explanation of Requirements of Proposed Rule**

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 95-02-15 to continue to require repetitive inspections to detect cracking of the wing front spar web above engine numbers 2 and 3, and to detect cracked or broken fasteners in the web; and repair, if necessary. The proposed AD also would continue to

provide for an optional terminating action for the repetitive inspections. The proposed AD would require various improved inspections. The improved inspections would be required to be accomplished in accordance with Revision 5 of the alert service bulletin described previously.

**Differences Between the Proposal and the Relevant Service Information**

Operators should note that, unlike the initial compliance time (specified in the alert service bulletin as within 15,000 total flight cycles or 6 months, whichever occurs later, for airplanes identified as Configuration A), the proposed AD would require that those airplanes be inspected prior to the accumulation of 13,000 total flight cycles or within 6 months. The 13,000 total flight cycle compliance threshold was established by AD 95-02-15, as a result of reports of cracking on affected airplanes that had accumulated between 13,700 and 22,000 total flight cycles. In light of these factors, the FAA finds that a 13,000 total flight cycle compliance threshold for initiating the required actions is warranted, in that it represents an appropriate interval of time allowable for affected airplanes to continue to operate without compromising safety.

**Cost Impact**

There are approximately 190 Boeing Model 747-100 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 95 airplanes of U.S. registry would be affected by this proposed AD.

The actions that are currently required by AD 95-02-15, and retained in this proposed AD, take approximately 70 work hours per airplane to accomplish, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be \$399,000, or \$4,200 per airplane, per inspection cycle.

For airplanes identified as Configuration A in the referenced alert service bulletin, the new actions that are proposed in this AD action would take approximately 60 work hours per airplane to accomplish, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the proposed requirements of this AD on those U.S. operators is estimated to be \$3,600 per airplane, per inspection cycle.

For airplanes identified as Configuration B in the referenced alert service bulletin, the new actions that are proposed in this AD action would take approximately 40 work hours per

airplane to accomplish, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of these new action proposed by this AD on U.S. operators is estimated to be \$2,400 per airplane, per inspection cycle.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Should an operator elect to accomplish the optional terminating action (fastener replacement between FSS 570 and FSS 684) that is provided by this AD action, it would take approximately 306 work hours to accomplish it, at an average labor rate of \$60 per work hour. The cost of required parts would be approximately \$15,478. Based on these figures, the cost impact of the optional terminating action will be \$33,838 per airplane.

### Regulatory Impact

The regulations proposed herein would 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 Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39-9134 (60 FR 9613, February 21, 1995), and by adding a new airworthiness directive (AD), to read as follows:

**Boeing:** Docket 97-NM-82-AD. Supersedes AD 95-02-15, Amendment 39-9134.

**Applicability:** Model 747-100 series airplanes; as listed in Boeing Alert Service Bulletin 747-57A2266, Revision 5, dated August 3, 1995; certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (g) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

**Compliance:** Required as indicated, unless accomplished previously.

To prevent fuel leakage onto an engine and a resultant fire, accomplish the following:

### Restatement of Requirements of AD 95-02-15, Amendment 39-9134:

(a) For airplanes on which 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; has not been accomplished: Prior to the accumulation of 13,000 total flight cycles, or within 9 months after March 23, 1995 (the effective date of AD 95-02-15, amendment 39-9134), or within 2,000 flight cycles after the immediately preceding inspection accomplished in accordance with AD 92-07-11, amendment 39-8207, whichever occurs latest, accomplish the inspections specified in paragraphs (a)(1), (a)(2), and (a)(3) of this AD in accordance with Boeing Service Bulletin 747-57A2266, Revision 3, dated March 31, 1994, or Revision 4, dated November 3, 1994. Repeat these inspections thereafter at intervals not to exceed 2,000 flight cycles until the inspections required by paragraph (c) or (d) of this AD, as applicable, are accomplished.

(1) Perform a detailed visual inspection to detect cracking of the wing front spar chords, stiffeners, and rib posts between the fastener heads between FSS 570 and FSS 684; and

(2) Perform an ultrasonic inspection of the web under the upper and lower chord footprints to detect cracking of the wing front spar web between FSS 570 and FSS 684; and

(3) Perform an ultrasonic inspection of the fasteners in the web-to-chords, and of the fasteners in the top two and bottom two rows in the web-to-stiffeners and web-to-rib posts of the wing front spar to detect cracked or broken fasteners between FSS 570 and FSS 684.

(b) For airplanes on which 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; has been accomplished: Within 18 months after accomplishing the terminating action specified in the original issue, Revision 1, or Revision 2 of the service bulletin, or within 9 months after March 23, 1995, whichever occurs later, accomplish the inspections specified in paragraphs (b)(1), (b)(2), and (b)(3) of this AD in accordance with Boeing Service Bulletin 747-57A2266, Revision 3, dated March 31, 1994, or Revision 4, dated November 3, 1994. Repeat these inspections thereafter at intervals not to exceed 2,000 flight cycles until the inspections required by paragraph (c) or (d) of this AD, as applicable, are accomplished.

(1) Perform a detailed visual inspection of the wing front spar chords, stiffeners, and rib posts between the fastener heads between FSS 570 and FSS 684; and

(2) Perform an ultrasonic inspection of the web under the upper and lower chord footprints to detect cracking of the wing front spar web between FSS 570 and FSS 636 and between FSS 675 and FSS 684; and

(3) Perform an ultrasonic inspection of the fasteners in the web-to-chords, and of the fasteners in the top two rows and bottom two rows in the web-to-stiffeners and web-to-rib posts of the wing front spar to detect cracked or broken fasteners between FSS 570 and FSS 636 and between FSS 675 and 684.

### New Requirements of This AD:

(c) For airplanes identified as Configuration A in Boeing Alert Service Bulletin 747-57A2266, Revision 5, dated August 3, 1995: Prior to the accumulation of 13,000 total flight cycles, or within 6 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 (c)(1), (c)(2), (c)(3), and (c)(4) of this AD, in accordance with Figure 3 of Boeing Alert Service Bulletin 747-57A2266, Revision 5, dated August 3, 1995 specified. 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 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 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 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]

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## 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