747–200C, 747–200F, 747–300, 747–400, 747–400D, 747–400F, 747SR, and 747SP series airplanes; certificated in any category; as identified in Boeing Alert Service Bulletin 747–54A2218, dated June 17, 2004.

Unsafe Condition

(d) This AD was prompted by reports of corroded, migrated, and rotated bearings for the dual side braces (DSB) in the inboard and outboard struts, a report of a fractured retainer for the eccentric bushing for one of the side links of a DSB, and reports of wear and damage to the underwing midspar fitting on the outboard strut. We are issuing this AD to prevent the loss of a DSB or underwing midspar fitting load path, which could result in the transfer of loads and motion to other areas of a strut, and possible separation of a strut and engine from the airplane during flight.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspections and Corrective Action

(f) At the times specified in Figure 1 of Boeing Alert Service Bulletin 747–54A2218, dated June 17, 2004, except as provided by paragraph (g) of this AD: Do the various inspections and other specified actions in the figure to detect discrepancies of the dual side braces, underwing midspar fittings, and associated parts, by doing all of the actions specified in Parts 1, 2, and 4; and the applicable corrective actions specified in Parts 3, 5, 6, and 7; of the Accomplishment Instructions of the service bulletin, except as provided by paragraph (h) of this AD. Repeat the inspections and other specified actions thereafter at the intervals specified in Figure 1 of the service bulletin. Accomplishment of any terminating action specified in Figure 1 of the service bulletin terminates the inspections and other specified actions.

(g) Where Boeing Alert Service Bulletin 747–54A2218, dated June 17, 2004, recommends an initial compliance threshold of ''within 24 months after the original issue date on this service bulletin'' for Parts 1 and 4 of the service bulletin, and of ''within 72 months after the original issue date on this service bulletin'' for Part 2 of the service bulletin, this AD requires an initial compliance threshold of ''within 24 months after the effective date of this AD'' for Parts 1 and 4 of the service bulletin and of ''within 72 months after the effective date of this AD'' for Part 2 of the service bulletin.

(h) If any damage or crack is found during any inspection or corrective action required by this AD, before further flight, repair in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 747–54A2218, dated June 17, 2004; except, where the service bulletin specifies to contact Boeing, before further flight, repair according to a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or according to data meeting the certification basis of the airplane approved by an Authorized Representative for the Boeing Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, Seattle ACO, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically refer to this AD.

Issued in Renton, Washington, on February 7, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–2762 Filed 2–11–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–262P]

21 CFR Part 1308

Schedules of Controlled Substances: Placement of Zopiclone Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to place the substance zopiclone, 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) and on an evaluation of the relevant data by DEA. If finalized, this action will impose the regulatory controls and criminal sanctions of Schedule IV on those who handle zopiclone and products containing zopiclone.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before March 16, 2005.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–262P'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to Deputy Administrator, Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov*. Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept electronic comments containing MS Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307–7183.

SUPPLEMENTARY INFORMATION: Zopiclone is a central nervous system depressant drug. On December 15, 2004, the Food and Drug Administration (FDA) approved (S)-zopiclone (or eszopiclone), the active (S) isomer of zopiclone, for marketing under the trade name Lunesta™. Eszopiclone will be marketed as a prescription drug product for the short-term treatment of insomnia.

Racemic (R, S) zopiclone, commonly known as zopiclone, is a pyrrolopyrazine derivative of the cyclopyrrolone class and is a mixture composed of equal proportions of two optical isomers identified as (S)-zopiclone (or eszopiclone) and (R)-zopiclone. Its chemical name is 1-piperazinecarboxylic, 4-methyl-, (5RS)-6-(5-chloro-2-pyridinyl)-6,7-dihydro-7-oxo-5H-pyrrolo [3,4-b]pyrazin-5yl ester (CAS number 43200–80–2). Eszopiclone is the most active component of the racemic (R,S) zopiclone.

Zopiclone and its (S) and (R) forms of optical isomers share with benzodiazepines (*e.g.* diazepam) substantial similarities in their pharmacological properties such as anxiolytic, sedative and hypnotic actions. In controlled clinical studies, zopiclone has been found to be superior to placebo on subjective measures of sleep latency and total sleep time. In

healthy human subjects, eszopiclone is rapidly absorbed with a time to peak concentration (t_{max}) of approximately 1 hour following oral ingestion (1–7.5 mg) and has an elimination half-life (t½) of approximately 6 hours.

In clinical trials, eszopiclone shows an adverse event profile comparable to that of other hypnotics. Some adverse effects of eszopiclone include hallucinations, amnesia, difficulty concentrating, memory impairment, depression, somnolence and accidental injury.

The abuse potential of zopiclone and its optical isomers is similar to those of the benzodiazepines and the nonbenzodiazepine hypnotics, zaleplon and zolpidem, that are all currently listed in Schedule IV of the CSA. It produces euphoria, alterations in mood, perception, memory and subjective effects in humans typical of other benzodiazepines with abuse potential in Schedule IV. Zopiclone is positively reinforcing in monkeys. Zopiclone generalizes to the discriminative stimulus effects of zolpidem and benzodiazepines such as diazepam, chlordiazepoxide, and midazolam in animals. Conversely, benzodiazepines, namely diazepam, nitrazepam and alprazolam, generalize to stimulus effects of zopiclone in animals.

Case reports of dependence and withdrawal effects to zopiclone have been published in the scientific literature. Some symptoms of zopiclone withdrawal include insomnia, anxiety, tremors, palpitations, and craving. Clinical trials indicate that withdrawal effects from eszopiclone are similar to those of benzodiazepines.

From 1995 to 2004, there was one zopiclone encounter by Federal law enforcement. It involved a seizure of four tablets contained in a square foil blister pack in the State of Washington in 2000.

On January 18, 2005, the Acting Assistant Secretary for Health, DHHS, sent the Deputy Administrator of DEA scientific and medical evaluation and a letter recommending that zopiclone and its isomers be placed into Schedule IV of the CSA. Enclosed with the January 18, 2005, letter was a document prepared by the FDA entitled, ''Basis for the Recommendation for Control of Zopiclone and its Optical Isomers 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)).

The correspondence from the Acting Assistant Secretary for Health to DEA dated January 18, 2005, confirmed that FDA approved the New Drug Application (NDA) for eszopiclone and issued an approval letter to the NDA sponsor on December 15, 2004.

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

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effects;

(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. (21 U.S.C. 811(c))

Based on the recommendation of the Acting Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, the Deputy Administrator of 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, zopiclone has a low potential for abuse relative to the drugs or other substances in Schedule III;

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

(3) Abuse of zopiclone may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III. (21 U.S.C. 812(b)(4))

Based on these findings, the Deputy Administrator of DEA concludes that zopiclone, including its salts, isomers, and salts of isomers, warrants control in Schedule IV of the CSA.

Interested persons are invited to submit their comments, objections or requests for a hearing 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 Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. In the event that comments, objections, or requests for a hearing raise one or more issues which the Deputy Administrator finds warrant a hearing, the 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.

Requirements for Handling Zopiclone

If this rule is finalized as proposed, zopiclone would be subject to Controlled Substances Act regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a Schedule IV controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with zopiclone, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with zopiclone, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations.

Security. Zopiclone would be subject to Schedule III–V security requirements and 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.

Labeling and Packaging. All labels and labeling for commercial containers of zopiclone which are distributed after finalization of this rule shall comply with requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

Inventory. Every registrant required to keep records and who possesses any quantity of zopiclone would be required to keep an inventory of all stocks of zopiclone on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations. Every registrant who desires registration in Schedule IV for zopiclone would be required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants are required to keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations.

Prescriptions. All prescriptions for zopiclone or prescriptions for products containing zopiclone would be required to be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21–1306.27. All prescriptions for zopiclone or products containing zopiclone issued after publication of the Final Rule, if authorized for refilling, would be limited to five refills.

Importation and Exportation. All importation and exportation of

zopiclone must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations.

Criminal Liability. Any activity with zopiclone not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on or after finalization of this proposed rule would be unlawful.

Regulatory Certifications

Executive Order 12866

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 12866, section 3(d)(1).

Regulatory Flexibility Act

The 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. Eszopiclone products will be prescription drugs used for the short term treatment of insomnia. Handlers of eszopiclone also handle other controlled substances used to treat insomnia which are already subject to the regulatory requirements of the CSA.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $115,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1995

This rule is not a major rule as defined by § 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.

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 DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES [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 adding a new paragraph (c)(51) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(51) Zopiclone	2784

* * * * *

Dated: February 9, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–2884 Filed 2–11–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

RIN 1010–AD09

Oil and Gas and Sulphur Operations on the Outer Continental Shelf (OCS)—Suspension of Operations (SOO's) for Ultra-Deep Drilling

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule.

SUMMARY: The MMS proposes to modify its regulations at 30 CFR 250.175, which govern SOO's for oil and gas leases on the OCS. The proposed revision will allow MMS to grant SOO's to lessees or operators who plan to drill ultra-deep wells. MMS proposes this revision because of the added complexity and costs associated with planning and drilling an ultra-deep well. MMS expects that this revision will lead to increased drilling of ultra-deep wells and increased domestic production.

DATES: MMS will consider all comments received by March 16, 2005. MMS may not fully consider comments received after March 16, 2005.

ADDRESSES: You may submit comments on the rulemaking by any of the following methods listed below. Please use the RIN 1010–AD09 as an identifier in your message. *See also* Public Comment Policy under Procedural Matters.

- MMS's Public Connect on-line commenting system, *https://ocsconnect.mms.gov.* Follow the instructions on the Web site for submitting comments.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions on the Web site for submitting comments.
- E-mail MMS at *rules.comments@mms.gov.* Use the RIN in the subject line.
- *Fax:* 703–787–1093. Identify with RIN.
- Mail or hand-carry comments to the Department of the Interior; Minerals Management Service; Attention: Rules Processing Team (RPT); 381 Elden Street, MS–4024; Herndon, Virginia 20170–4817. Please reference ''Oil and Gas and Sulphur Operations on the Outer Continental Shelf (OCS)—Suspension of Operations (SOO's) for Ultra-deep Drilling— AD09'' in your comments.

You may also send comments on the information collection aspects of this rule directly to the Office of