Applicability

(c) This AD applies to Rolls-Royce plc models RB211 Trent 875–17, –877–17, –884–17, –884B–17, –892–17, –892B–17, and –895–17 turbofan engines with fuel-to-oil heat exchangers, part numbers 55003001–1 and 55003001–11, installed. These engines are installed on, but not limited to, Boeing 777 series airplanes.

Reason

(d) This AD results from the risk of engine fuel-to-oil heat exchanger (FOHE) blockage. We are issuing this AD to prevent ice from blocking the FOHE, which could result in an unacceptable engine power loss, and loss of control of the airplane.

Actions and Compliance

(e) Unless already done, within 6,000 flight hours after the effective date of this AD, but no later than January 1, 2011, replace the FOHE, P/N 55003001–1 or 55003001–11, with an FOHE that does not have a P/N or equivalent listed in this AD.

FAA AD Differences

(f) This AD differs from the Mandatory Continuing Airworthiness Information (MCAI) by requiring replacing the FOHE within 6,000 flight hours after the effective date of this AD, but no later than January 1, 2011.

Other FAA AD Provisions

(g) *Alternative Methods of Compliance (AMOCs):* The Manager, Engine Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Related Information

(h) Refer to MCAI Airworthiness Directive 2009–0142, dated July 13, 2009, and Rolls-Royce plc Alert Service Bulletin RB.211–79–AG257, dated June 24, 2009, for related information. Contact Rolls-Royce plc, P.O. Box 31, DERBY, DE24 8BJ, UK; telephone 44 (0) 1332 242424; fax 44 (0) 1332 249936, for a copy of this service information.

(i) Contact James Lawrence, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; *e-mail: james.lawrence@faa.gov*; telephone (781) 238–7176; fax (781) 238–7199, for more information about this AD.

Issued in Burlington, Massachusetts, on July 17, 2009.

Peter A. White,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E9–17470 Filed 7–22–09; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–327]

Schedules of Controlled Substances: Placement of Fospropofol Into Schedule IV

AGENCY: Drug Enforcement Administration, 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 fospropofol, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, 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 would impose the regulatory controls and criminal sanctions of schedule IV on those who handle fospropofol and products containing fospropofol.

DATES: Written comments must be postmarked on or before August 24, 2009, and electronic comments must be sent on or before midnight Eastern time August 24, 2009.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–327'' on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, Virginia 22152. Comments may be sent to DEA 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 Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern Time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at midnight Eastern time on the day the comment period closes. Commenters in time zones other than Eastern time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, *etc.*) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, *etc.*) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the DEA's public docket file. Please note that the Freedom of

Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the ''For Further Information'' paragraph.

Background

On December 12, 2008, the Food and Drug Administration (FDA) approved fospropofol for marketing under the trade name Lusedra® in the United States as a drug product indicated for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures. Lusedra® will be available as 35 milligrams/ml of fospropofol disodium solution for intravenous (i.v.) use. Fospropofol acts as a central nervous system (CNS) depressant and is classified as a sedative-hypnotic.

Fospropofol, 2,6-diisopropopylphenoxymethyl phosphate disodium, is a water soluble, phosphono-O-methyl prodrug of propofol. It is metabolized in the body to propofol, the active metabolite. Propofol has been available for medical use in the United States since 1989 and is not currently a controlled substance.

The pharmacological effects of fospropofol are attributed to the pharmacological actions of propofol. Fospropofol elicits behavioral effects similar to methohexital and midazolam, schedule IV sedative-hypnotics.

The receptor binding profile of fospropofol has been shown to be similar to that of propofol (DHHS evaluation, 2008). Propofol binds to γ-aminobutyric acid ($GABA_A$) receptor and acts as a modulator by potentiating the activity of GABA at this receptor. Other psychoactive drugs, *e.g.,* barbiturates, benzodiazepines, and volatile anesthetics, potentiate activity of GABA at the $GABA_A$ receptor. Propofol also inhibits the activity of the N-methyl-D-asparate (NMDA) receptor; as does ketamine, another anesthetic with significant abuse potential.

Since propofol is the active metabolite of fospropofol, the abuse potential of fospropofol is comparable to that of propofol. Animal self-administration studies demonstrated that the reinforcing effects of propofol are relatively low and comparable to midazolam and other schedule IV benzodiazepines. Both drug-naïve and methohexital-trained (schedule IV barbiturate) rats self-administer propofol under a fixed ratio schedule. In baboons after substituting for cocaine, subanesthetic doses of propofol maintained low-to-high levels of self-administration.

Schedule IV sedative-hypnotics like methohexital and midazolam are known to produce euphoric moods as adverse events and have histories of abuse in the U.S. and elsewhere. The adverse events associated with fospropofol are similar to those experienced with schedule IV sedative-hypnotics. In humans, the most commonly reported adverse events were paresthesia (abnormal skin sensations, *e.g.,* burning, itching), pruritus (itching), headache, and dizziness. In nine clinical studies in healthy humans (n = 273), subjects were administered intravenous (i.v.) fospropofol. Within that population, 0.7 percent reported euphoria and disorientation adverse events (DHHS evaluation, 2008).

The current abuse profiles of propofol, the active metabolite of fospropofol, indicate that propofol is abused by medical professionals since they have access to the drug in medical facilities which perform anesthesia, according to the Adverse Event Reporting System (AERS) DataMart database (DHHS evaluation, 2008). Although the fospropofol product Lusedra® will be marketed as an i.v. dosage form, in the New Drug Application (NDA) submitted to the DHHS, it has been demonstrated that after oral administration fospropofol is active in the body. The oral activity of fospropofol increases the likelihood of its abuse by other routes of administration and its use to commit other crimes (*e.g.,* date-rape).

Withdrawal symptoms observed upon ceasing long-term administration of a substance are indicative of a substance's ability to produce physical dependence. The effects of long-term administration of fospropofol were not studied in the clinical trials so the dependence potential of fospropofol is best demonstrated by the withdrawal syndrome associated with long-term use of propofol. There have been published reports of withdrawal symptoms upon abrupt cessation of administration of propofol after several days of treatment. The symptoms included agitation, tremors, tachycardia, tachypnea, hyperpyrexia, confusion, and hallucinations. These symptoms are similar to the symptoms observed upon withdrawal from benzodiazepines. Withdrawal symptoms improve once administration of propofol is reinitiated. A delusional state lasting up to seven days may occur before full mental functioning returns.

References to the above studies may be found in the Health and Human Services scheduling recommendation and DEA's independent analysis, both of which are available on the electronic docket associated with this rule making.

Since fospropofol is a new molecular entity, there has been no evidence of diversion, abuse, or law enforcement encounters involving the drug. On February 27, 2009, the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that fospropofol be placed into schedule IV of the CSA. Enclosed with the February 27, 2009, letter was a document prepared by the FDA entitled, ''Basis for the Recommendation for Control of Fospropofol and Its Salts in Schedule IV of the CSA.'' The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

The factors considered by the Assistant Secretary of Health and DEA with respect to fospropofol 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 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. Fospropofol has a low potential for abuse relative to the drugs or substances in schedule III. Although there is no direct comparison to a schedule III substance, this finding is based on the demonstration of the abuse potential of propofol, the active metabolite, relative to the schedule IV substances, methohexital and midazolam;

2. Fospropofol has a currently accepted medical use in treatment in the U.S.; Fospropofol under the trade name Lusedra® was approved for marketing as a product indicated for monitored anesthesia care by FDA on December 12, 2008; and

3. Abuse of fospropofol may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III. This finding is based on

the symptoms exhibited upon withdrawal from propofol.

Based on these findings, the Deputy Administrator of DEA concludes that fospropofol, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible warrants control in schedule IV of the CSA. (21 U.S.C. 812(b)(4))

Comments and Requests for 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 the Administrative Procedure Act (5 U.S.C. 556 and 557). All persons are invited to submit their comments or objections with regard to this proposal. Requests for a hearing may be submitted by interested persons and must conform to the requirements of 21 CFR 1308.44 and 1316.47. The request should state, with particularity, the issues concerning which the person desires to be heard and the requestor's interest in the proceeding. Only interested persons, defined in the regulations as those ''adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),'' may request a hearing. 21 CFR 1308.42. Please note that DEA may grant a hearing only ''for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable'' pursuant to 21 U.S.C. 811(a). All correspondence regarding this matter including comments, objections, and requests for hearing should be submitted to DEA using the address information provided above.

Requirements for Handling Fospropofol

If this rule is finalized as proposed, fospropofol would be subject to CSA 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 fospropofol, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with fospropofol, would need to be registered to conduct such activities in accordance with 21 CFR part 1301.

Security. Fospropofol would be subject to Schedules III–V security requirements and would need to be manufactured, distributed, and stored in accordance with 21 CFR 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77.

Labeling and Packaging. All labels and labeling for commercial containers of fospropofol which are distributed on or after finalization of this rule would need to comply with requirements of 21 CFR 1302.03–1302.07.

Inventory. Every registrant required to keep records and who possesses any quantity of fospropofol would be required to keep an inventory of all stocks of fospropofol on hand pursuant to 21 CFR 1304.03, 1304.04 and 1304. Every registrant who desires registration in schedule IV for fospropofol would be required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants would be required to keep records pursuant to 21 CFR 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23.

Prescriptions. All prescriptions for fospropofol or prescriptions for products containing fospropofol would be required to be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21, 1306.22–1306.27.

Importation and Exportation. All importation and exportation of fospropofol would need to be in compliance with 21 CFR part 1312.

Criminal Liability. Any activity with fospropofol not authorized by, or in violation of, the CSA 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. 601–612), 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. Fospropofol products will be used for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures. Handlers of fospropofol will also handle other controlled substances used for sedation 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 $120,000,000 or more (adjusted for inflation) 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.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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

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 in paragraph (c), by redesignating paragraphs (c)(23) through (c)(51) as paragraphs (c)(24) through (c)(52) and adding a new paragraph (c)(23) as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(23) Fospropofol 2138

* * * * *

Dated: July 16, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–17538 Filed 7–22–09; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–HQ–OAR–2003–0062; FRL–8934–3]

RIN 2060–AP65

Implementation of the New Source Review (NSR) Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$); Proposal To Extend Administrative Stay

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to extend for an additional nine months the existing administrative stay of the ''grandfathering'' provision for particulate matter less than 2.5 micrometers ($PM_{2.5}$) requirements in the Federal Prevention of Significant Deterioration (PSD) program published in the **Federal Register** on May 16, 2008 as part of the final rule entitled, ''Implementation of the New Source Review (NSR) Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$).'' The grandfathering provision under the Federal PSD program allows the permitting authority to review PSD permit applications received before July 15, 2008 according to EPA's 1997 policy of satisfying the requirements for particulate matter less than 10 micrometers (PM_{10}) as a surrogate for meeting the new requirements for $PM_{2.5}$.

The existing administrative stay is in effect for three months; that is, from June 1, 2009 until September 1, 2009. This action proposes to extend the existing administrative stay by an additional nine months, which we believe will allow for sufficient time for EPA to propose, take public comment on, and issue a final action concerning the repeal of the grandfathering provision for $PM_{2.5}$ in the Federal PSD program.

DATES: Comments must be received on or before August 24, 2009.

Public Hearing. If anyone contacts EPA requesting the opportunity to speak at a public hearing concerning the proposed regulation by August 3, 2009, we will hold a public hearing on August 7, 2009. If a hearing is held, the record for the hearing will remain open until September 8, 2009.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2003–0062, by one of the following methods:

- *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *E-mail: a-and-r-docket@epa.gov.*
- *Fax:* (202) 566–1741.
- *Mail:* Air and Radiation Docket, Environmental Protection Agency, Mail code 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460.
- *Hand Delivery:* EPA Docket Center, Public Reading Room, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to the applicable docket. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Public Hearing. If a public hearing is held, it will be held at the U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20004.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the EPA Docket Center, Public Reading Room, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1742, and the telephone number for the Air Docket is (202) 566–1744.

FOR FURTHER INFORMATION CONTACT: Mr. Dan deRoeck, Air Quality Policy Division, (C504–03), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number (919) 541–5593; fax number (919) 541–5509; or e-mail address: *deroeck.dan@epa.gov.*

To request a public hearing or information pertaining to a public hearing on this document, contact Ms. Pamela Long, Air Quality Policy Division, Office of Air Quality Planning and Standards (C504–03), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number (919) 541–0641; fax number (919) 541–5509; e-mail address: *long.pam@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

Entities affected by this proposed action are the owners and operators of proposed new sources and