products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) 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.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2005–15–15 Boeing: Amendment 39–14204. Docket No. FAA–2005–20138; Directorate Identifier 2004–NM–167–AD.

Effective Date

(a) This AD becomes effective September 1, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 757–200, –200PF, and –200CB series airplanes, line numbers 1 through 735 inclusive, certificated in any category; equipped with Pratt & Whitney or Rolls-Royce engines.

Unsafe Condition

(d) This AD was prompted by a report indicating that, due to an incorrect listing in the illustrated parts catalog, persons performing maintenance on the engine strut(s) could have installed an incorrect upper link forward fuse pin having part number (P/N) 311N5501–2. We are issuing this AD to prevent a ruptured wing box, due to the engine not separating safely during certain emergency landing conditions, which could lead to a fuel spill and consequent fire.

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.

Inspection of Fuse Pin

(f) Within 24 months after the effective date of this AD, perform a detailed inspection to determine the P/N of the upper link forward fuse pins of the engine struts, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 757–54–0048, dated May 13, 2004, except as provided in paragraphs (g) and (h) of this AD.

Note 1: For the purposes of this AD, a detailed inspection is: ''An intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirror, magnifying lenses, etc., may be necessary. Surface cleaning and elaborate procedures may be required.''

(1) If the fuse pin is P/N 311N5501–1 or P/N 311N5060–1, no further action is required for that fuse pin.

(2) If the fuse pin is P/N 311N5501–2, prior to further flight, replace the fuse pin with a new or serviceable fuse pin, P/N 311N5501–1, in accordance with the Accomplishment Instructions of the service bulletin.

(3) If the P/N of the fuse pin cannot be determined by inspection, use a tool such as an inside reading micrometer to determine the inside diameter (ID) of the fuse pin bore.

(i) If the ID of the fuse pin bore is greater than or equal to 0.850 inch, no further action is required for that fuse pin.

(ii) If the ID of the fuse pin bore is less than 0.850 inch, prior to further flight, replace the fuse pin as specified in paragraph (f)(2) of this AD.

(g) Where Boeing Special Attention Service Bulletin 757–54–0048, dated May 13, 2004, permits the use of an ''approved equivalent procedure'' for access and replacement of the fuse pin(s), this AD requires that access and replacement be done in accordance with the instructions of the aircraft maintenance manual (AMM) as specified in the service bulletin.

Optional Alternative to Inspections

(h) Instead of the inspections required by paragraph (f) of this AD, a review of the airplane maintenance records is acceptable if the P/N of the fuse pins can be positively determined from that review.

Parts Installation

(i) As of the effective date of this AD, no person may install a fuse pin, P/N 311N5501–2, on any airplane identified in the applicability of this AD.

Alternative Methods of Compliance (AMOCs)

(j)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, 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 repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Material Incorporated by Reference

(k) You must use Boeing Special Attention Service Bulletin 757–54–0048, dated May 13, 2004, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. To view the AD docket, go to the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW, room PL–401, Nassif Building, Washington, DC. To review copies of the service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on July 14, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–14685 Filed 7–27–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–267F]

21 CFR Part 1308

Schedules of Controlled Substances: Placement of Pregabalin Into Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to place the substance pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid], including its salts, and all products containing pregabalin into Schedule V of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule V will be applicable to the manufacture, distribution, dispensing, importation and exportation of pregabalin and products containing pregabalin.

DATES: This rule is effective July 28, 2005.

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

SUPPLEMENTARY INFORMATION:

Background

On December 31, 2004, the Food and Drug Administration (FDA) approved pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid] for marketing under the trade name Lyrica™. Lyrica™ will be marketed in the United States as a prescription drug product for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN). Pregabalin has recently been placed on the market in some European countries for the treatment of epilepsy and neuropathic pain.

On April 4, 2005, the Acting Assistant Secretary for Health of the Department of Health and Human Services (DHHS), sent the Administrator of the DEA a letter recommending that pregabalin, and its salts, be placed into Schedule V of the CSA. Enclosed with the April 4, 2005, letter was a document prepared by the FDA entitled, ''Basis for the Recommendation for Control of Pregabalin in Schedule V 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)).

Based on the recommendation of the Acting Assistant Secretary for Health and an independent review of the available data by the DEA, the Deputy Administrator of the DEA, in a May 13, 2005, **Federal Register** Notice of Proposed Rulemaking (70 FR 25502), proposed placement of pregabalin into Schedule V of the CSA. The proposed rule provided an opportunity for all interested persons to submit their comments, objections or requests for hearing to be received by the DEA on or before June 13, 2005.

Comments Received

The DEA received two comments in response to the Notice of Proposed Rulemaking. One commenter stated that the DEA should not minimize the similarity in effects produced by pregabalin and diazepam and should place pregabalin in Schedule IV of the CSA.

The DEA does not agree. Careful consideration of all the available data suggests that pregabalin has less abuse potential than Schedule IV substances. Pregabalin does not substitute for benzodiazepines in benzodiazepine-dependent animals. Data from clinical trials suggest that some of pregabalin's positive psychic effects are limited and do not continue with time or continued drug use. The data are consistent with a substance that could be abused intermittently for reward, but not for reinforcement. In addition, withdrawal effects of pregabalin are less severe than with other substances currently controlled in Schedule IV.

Another commenter stated that, in their experience with pregabalin in clinical trials, pregabalin does not demonstrate any risk that would merit being considered a scheduled drug.

The DEA does not agree. Preclinical studies indicated that pregabalin is transiently and sporadically self-administered at rates greater than vehicle but substantially lower than active comparators pentobarbital (CII) and methohexital (CIV). In clinical trials, pregabalin produces some pharmacological effects characteristic of diazepam and alprazolam and is likely to be abused for its positive psychic effects. The percentage of individuals that experienced acute euphoric effects was unusually high for pregabalin in clinical trials. Pregabalin also produced dizziness, somnolence, dry mouth, edema, blurred vision, weight gain and attentional problems more frequently than placebo. These data suggest that pregabalin does have sufficient abuse potential to warrant control under the CSA. The DHHS recommended control in Schedule V of the CSA and the DEA concurs.

Scheduling of Pregabalin

Relying on the scientific and medical evaluation and 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 the DEA, and after a review of the comments received in response to the Notice of Proposed Rulemaking, the Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Pregabalin has a low potential for abuse relative to the drugs or other substances in Schedule IV;

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

(3) Abuse of pregabalin may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV. (21 U.S.C. 812(b)(5))

Based on these findings, the Deputy Administrator of the DEA concludes that pregabalin, including its salts, and all products containing pregabalin, warrant control in Schedule V of the CSA.

In order to make pregabalin pharmaceutical products available for medical use as soon as possible, the Schedule V controls for pregabalin will be effective July 28, 2005. In the event that the regulations impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the Schedule V regulations regarding pregabalin. The applicable regulations are as follows:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, conducts research or instructional activities or chemical analysis or proposes to engage in such activities with pregabalin, must submit an application for Schedule V registration in accordance with part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before August 29, 2005, and may continue their activities until the DEA has approved or denied that application.

Security. Pregabalin is 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), 1301.76, and 1301.77 of Title 21 of the Code of Federal Regulations on and after July 28, 2005.

Labeling and Packaging. All labels and labeling for commercial containers of pregabalin 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 pregabalin must keep an inventory of all stocks of pregabalin on

hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on and after July 28, 2005. Every registrant who desires registration in Schedule V for pregabalin is required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on and after July 28, 2005.

Prescriptions. All prescriptions for pregabalin or prescriptions for products containing pregabalin must be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21, 1306.23–1306.27.

Importation and Exportation. All importation and exportation of pregabalin must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on and after July 28, 2005.

Criminal Liability. Any activity with pregabalin not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on and after July 28, 2005, shall be unlawful.

Regulatory Certifications

Administrative Procedure Act

The Administrative Procedure Act permits an agency to make a rule effective upon the date of publication when the agency finds good cause exists and publishes its findings with the rule (5 U.S.C. 553(d)(3)). As noted previously, on December 31, 2004, the FDA approved pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid] for marketing under the trade name Lyrica. On April 4, 2005, the Acting Assistant Secretary for Health of the DHHS sent the Administrator of the DEA a scientific and medical evaluation and a scheduling recommendation that pregabalin, and its salts, be placed in Schedule V of the CSA. Since this is a new drug not previously available in the United States and the first drug product specifically approved for the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN), in order to prevent harm to the public health and safety by delaying the availability of this new drug, the DEA finds good cause to make this Final Rule effective immediately upon publication.

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 final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Pregabalin products will be prescription drugs used for the treatment of neuropathic pain. Handlers of pregabalin often handle other controlled substances used to treat pain which are already subject to the regulatory requirements of the CSA.

Pregabalin is a new drug in the United States; recent approval of Lyrica™ by the FDA will allow it to be marketed once it is placed into Schedule V of the CSA. This final rule will allow medical access to a new pharmaceutical product.

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 1996

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 amends 21 CFR part 1308 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 1308.15 is amended by adding a new paragraph (e) to read as follows:

§ 1308.15 Schedule V.

* * * * *

(e) *Depressants.* Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(1) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid] 2782

(2) [Reserved]

Dated: July 22, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–15036 Filed 7–27–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9186]

RIN 1545–BD42

Qualified Amended Returns; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to a correction to temporary regulations.