

it is determined that this proposal would not have federalism implications under Executive Order 13132.

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 adding the following new airworthiness directive:

McDonnell Douglas: Docket 2001–NM–130–AD.

Applicability: Model MD–90–30 airplanes, certificated in any category; as identified in Boeing Service Bulletin MD90–24–007, Revision 02, dated July 16, 2001.

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 (b) 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 arcing between circuit breaker terminals and adjacent equipment and structure located on the generator control rack in the electrical/electronics compartment, and consequent electrical shock to maintenance personnel during maintenance operations, accomplish the following:

Installation

(a) Within one year after the effective date of this AD, install two arcing protection brackets below and behind the circuit breakers located in the generator control rack in the electrical/electronics compartment per the Accomplishment Instructions of McDonnell Douglas Service Bulletin MD90–24–007, Revision 02, dated July 16, 2001.

Note 2: Installation of two arcing protection brackets below and behind the circuit breakers located in the generator control rack in the electrical/electronics compartment per the Accomplishment Instructions of Boeing Service Bulletin MD90–24–007, dated February 7, 1996, or Revision 01, dated August 31, 2000, is considered acceptable for compliance with the requirements of this AD.

Alternative Methods of Compliance

(b) 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, Los Angeles Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

Special Flight Permit

(c) Special flight permits may be issued in accordance with §§ 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 March 14, 2002.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 02–6795 Filed 3–20–02; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Parts 200 and 212

[Docket OST–2002–11741]

Standards for Approving International Charter Flights; Petition of the National Air Carrier Association for Rulemaking

AGENCY: Office of the Secretary, DOT.

ACTION: Petition for rulemaking; request for comments.

SUMMARY: The Department is inviting comments on the petition for rulemaking filed by the National Air Carrier Association (NACA) to add, delete and amend certain provisions of 14 CFR Parts 200 and 212 of the Department's Regulations. In its petition, NACA proposes, among other things, changes in the definitions and standards the Department uses in determining whether to grant or deny foreign air carrier requests to conduct certain types of international charter flights. In order that we may have a complete record on which to base our decision on NACA's petition, we solicit the views of all interested persons and entities, including direct air carriers (both U.S. and foreign), indirect air carriers (both U.S. and foreign), trade associations, labor unions, travel agents, shippers, communities, and the general public, on the proposals set forth in that petition. The proposal is in OST Docket 2002–11741 and can be accessed via the internet by searching Docket 11741 at the DOT Docket website (<http://dms.dot.gov>). Hard copies may also be obtained by calling the contact person listed below.

DATES: Comments to the Petition for Rulemaking are due May 6, 2002. If comments are filed, reply comments are due June 4, 2002.

ADDRESSES: To make sure your comments and related material are not entered more than once in the docket, please submit them (marked with docket number OST–2002–11741) by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation, Room PL–401, 400 Seventh Street SW., Washington, DC 20590.

(2) By hand delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) Electronically through the Web Site for the Docket Management System at <http://dms.dot.gov>. Comments must be filed in Docket OST–2002–11741, U.S. Department of Transportation, 400 7th St. SW., Washington, DC 20590. Late filed comments will be considered to the extent possible. Due to security procedures in effect since October 2001 on mail deliveries, mail received through the Postal Service may be subject to delays. Commenters should consider using an express mail firm to ensure the timely filing of any

comments not submitted electronically or by hand.

FOR FURTHER INFORMATION CONTACT:

Gordon Bingham, Foreign Air Carrier Licensing Division, U.S. Department of Transportation, Room 6412, 400 Seventh Street, SW., Washington, DC 20590. Telephone (202) 366-2404.

Issued in Washington, DC on March 15, 2002.

Read C. Van De Water,

Assistant Secretary for Aviation and International Affairs.

[FR Doc. 02-6820 Filed 3-20-02; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR PART 1308

[DEA-225P]

**Schedule of Controlled Substances:
Proposed Rule: Rescheduling of
Buprenorphine From Schedule V to
Schedule III**

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to increase the regulatory controls placed on buprenorphine by rescheduling buprenorphine from a Schedule V narcotic to a Schedule III narcotic. This proposed action is based on a formal rescheduling recommendation by the Department of Health and Human Services (DHHS) and a DEA review indicating that buprenorphine meets the definition of a Schedule III narcotic. If finalized, this action will impose the regulatory controls and criminal sanctions of a Schedule III narcotic on those person who handle buprenorphine or products containing buprenorphine.

DATES: Comments must be received by April 22, 2002.

ADDRESSES: Comments should be submitted to the 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:

What Is Buprenorphine?

Buprenorphine is a derivative of thebaine, a major constituent of opium, presently marketed in the United States as an injectable formulation under the brand name of Buprenex® for the treatment of pain. It is classified as a narcotic agonist-antagonist, or partial agonist, with an analgesic potency far greater than morphine (generally reported to be about 20 to 30 times that of morphine sulfate in humans). DEA placed buprenorphine in Schedule V of the Controlled substances Act (CSA) in 1985 (50 FR 8104).

Buprenorphine has also been investigated for the treatment of narcotic addiction. Two New Drug Applications (NDA) have been submitted to the Food and Drug Administration (FDA) for this indication. Applications for marketing approval for these high-dose sublingual tablet products remain pending at FDA. However, approvable letters have been issued for both products and they are likely to receive final marketing approval in 2002.

Why Is DEA Issuing This Notice?

As part of the NDA review process for the high-dose sublingual tablet formulations for buprenorphine, the FDA reviewed and evaluated the scientific and medical data relating to scheduling under the CSA pursuant to 21 U.S.C. 811(b), (c), and (f). Since the original review conducted by the FDA in the early 1980s (prior to the marketing of Buprenex®), a substantial amount of human experience with buprenorphine products as well as a number of scientific studies have provided new information. These data have prompted a reevaluation of buprenorphine's status under the CSA. The eight factors used to determine the appropriate placement of buprenorphine under the CSA include:

- (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 physic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

On December 4, 2001, the Assistant Surgeon General and Acting Principal

Deputy Assistant Secretary for Health, Department of Health and Human Services (DHHS), Arthur J. Lawrence, signed and forwarded a letter to the DEA recommending that buprenorphine be rescheduled as a Schedule III substance. This recommendation was based on FDA's scientific and medical evaluation. After considering the FDA's evaluation and the DHHS scheduling recommendation and reviewing all the available relevant data regarding the eight factors determinative of control (21 U.S.C. 811(b)(c)), the DEA concludes that buprenorphine should be placed in Schedule III of the CSA.

Why Did DEA Conclude That Buprenorphine Should Be Placed in Schedule III of the Controlled Substances Act?

The DEA found that buprenorphine met the definition of a Schedule III substance. In accordance with 21 U.S.C. 812(b):

1. Buprenorphine has a potential for abuse less than the drugs or other substances in Schedule I or II.

Buprenorphine is a long-acting partial agonist with a high affinity for and slow dissociation from opioid receptors.

Buprenorphine produces effects similar to other pure mu agonists (like morphine or hydromorphone) including euphoria, drug liking, respiratory depression, pupillary constriction and sedation. It is recognized as morphine or heroin-like by experienced narcotic abusers.

Little abuse or diversion of buprenorphine has been noted in the U.S. (reflecting very limited prescription, distribution and product formulation: only low-dose injectable buprenorphine has been marketed). However, significant abuse of buprenorphine has been reported in many countries where it has been more available and other formulations have been marketed. In those countries, buprenorphine has been abused via the intravenous, sublingual, intranasal and inhalation routes by many abuser populations. Buprenorphine products have been diverted from legitimate channels through theft, doctor shopping and fraudulent prescriptions. Significant amounts of buprenorphine have been trafficked across international borders and law enforcement authorities have seized large amounts of buprenorphine involved in these activities.

The above data suggest that the abuse potential of buprenorphine is high and closely resembles other narcotics in Schedule II. However, buprenorphine effects are less dose-dependent than pure mu agonists and a "ceiling effect"