DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Removal of Thebaine-Derived Butorphanol from Schedule II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to remove thebaine-derived butorphanol from Schedule II of the Controlled Substances Act (CSA). This action is based on a recommendation from the Assistant Secretary for Health, Department of Health and Human Services (DHHS), that thebaine-derived butorphanol be decontrolled from Schedule II. As a result of this final rule, regulatory controls and criminal sanctions pertaining to Schedule II substances will not be applicable to thebaine-derived butorphanol.

EFFECTIVE DATE: July 14, 1992.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Butorphanol is an agonist/antagonist, narcotic analgesic used to treat moderate to severe pain. To date, butorphanol marketed in the United States has been produced by totally synthetic means. When synthetic butorphanol was approved for marketing, no recommendation was made by DHHS for scheduling this drug under the CSA. In addition, there was no information indicating that butorphanol could be derived from thebaine, an opium constituent. As a result, synthetic butorphanol has never been considered a controlled substance under the CSA.

On May 16, 1990, a petition was filed with the DEA requesting that butorphanol derived from thebaine be decontrolled. The petitioner noted that new chemical manufacturing information indicated that butorphanol could be manufactured from thebaine. As such, the thebaine-derived butorphanol would be a Schedule II substance since 21 U.S.C. 812(c) Schedule II(a)(1) includes "opium and opiate, and any salt, compound, derivative or preparation of opium or opiate."

On February 15, 1991, in accordance with 21 U.S.C. 811(b), the Administrator of the DEA requested that the Assistant Secretary for Health conduct a scientific and medical evaluation of thebaine-derived butorphanol and provide the DEA with a recommendation concerning the scheduling of this drug. On October 28, 1991, following a review of relevant medical and scientific data, the Assistant Secretary for Health recommended that thebaine-derived butorphanol be decontrolled from Schedule II.

Accordingly, on April 3, 1992, the Administrator published a notice in the **Federal Register** proposing to remove thebaine-derived butorphanol from Schedule II of the CSA. The notice provided a 60-day period during which comments and objections to the proposed rulemaking could be sent to the Administrator. As of June 3, 1992 the Administrator did not receive any comments or objections regarding the proposal to remove thebaine-derived butorphanol from Schedule II of the CSA.

The Administrator of the DEA hereby certifies that this final rule will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act 5 U.S.C. 801 *et seq.* This scheduling matter is a formal action required by statute to be made on the record after opportunity for an agency hearing. It is not a major rule for purposes of Executive Order (E.O.) 12291. Accordingly, it has not been submitted for review by the Office of Management and Budget (OMB) pursuant to the provisions of Executive Order 12291. This matter is not subject to those provisions of Executive Order 12778, which are contingent upon review by OMB. As a formal rulemaking, this action is not subject to the moratorium on regulations ordered by the President in his memorandum of January 28, 1992.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this matter does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Preparation 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 the DEA by Department of Justice Regulations (28 CFR 0.100), the Administrator hereby orders that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b)

2. Section 1308.12(b)(1) introductory text is revised to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following:

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Dated: July 6, 1992.

Robert C. Bonner,

Administrator, Drug Enforcement Administration.

[FR Doc. 92-16485 Filed 7-13-92; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 5

[T.D. ATF-326; Re: Notice No. 725]

RIN 1512-AA96

Standards of Fill for Distilled Spirits

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule.

SUMMARY: ATF is amending the standard of fill regulations for distilled spirits in 27 CFR part 5 to authorize a 355 milliliter (approximately 12 fluid ounces) size for cans only. The 375 milliliter size and larger sizes will no longer be permitted for cans.

EFFECTIVE DATE: September 1, 1992.

FOR FURTHER INFORMATION CONTACT: Dick Langford or Gail Hosey, Distilled Spirits and Tobacco Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20091-0221, telephone (202) 927-8210.

SUPPLEMENTARY INFORMATION:

Background

Section 105(e) of the Federal Alcohol Administration Act (FAA Act) 27 U.S.C. 205(e) authorizes the Secretary of the