

traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in East Point, Georgia, on September 9, 1982.

George R. LaCaille,
Acting Director, Southern Region.

[FR Doc. 82-25645 Filed 9-17-82; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Rescheduling of Buprenorphine From Schedule II to Schedule V of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration (DEA) proposes to reschedule the narcotic drug, buprenorphine, from Schedule II to V of the Controlled Substances Act (21 U.S.C. 801 *et seq.*). This action is initiated upon DEA's receipt of a letter from the Assistant Secretary for Health, Department of Health and Human Services (DHHS), recommending that buprenorphine be rescheduled from Scheduled II to Schedule V. DEA's final decision concerning the relative abuse potential of buprenorphine will take account of the Assistant Secretary's recommendation and any information received in response to this proposal. The effects of this rule would be to require that the manufacture, distribution, dispensing, security, registration, record keeping, inventory, exportation and importation of this drug be subject to controls for Schedule V narcotic substances.

DATE: Comments and objections must be received on or before November 19, 1982.

ADDRESS: Comments and objections should be submitted in quintuplicate to the Acting Administrator, Drug Enforcement Administration, 1405 I Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Buprenorphine is controlled in Schedule II of the Controlled Substances Act (CSA) under section 202, Schedule II(a)(1) as a "derivative * * * of opium or opiate."

On May 12, 1982, the Assistant Secretary for Health, on behalf of the Secretary, Department of Health and Human Services, sent a letter to the Acting Administrator of the Drug Enforcement Administration recommending that buprenorphine be rescheduled into Schedule V and continue to be defined as a narcotic. The letter is set forth below:

May 12, 1982

Mr. Francis M. Mullen, Jr.,
Acting Administrator, Drug Enforcement Administration, 1405 Eye Street, N.W., Washington, D.C. 20537.

Dear Mr. Mullen: Pursuant to the Controlled Substances Act 21 U.S.C. 811(f), this letter is notification that the Food and Drug Administration has approved a New Drug Application for buprenorphine, an analgesic drug with a potential for abuse. Buprenorphine is currently listed in Schedule II of the Act by virtue of its derivation from the Schedule II opioid precursor thebaine. The Food and Drug Administration has recommended that buprenorphine be rescheduled into Schedule V and continue to be defined a narcotic. The Schedule V recommendation is based on findings that buprenorphine has a low potential for abuse relative to the drugs or other substances in Schedule IV, that buprenorphine has a currently accepted medical use in treatment in the United States, and that abuse of buprenorphine may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV. The recommendation that buprenorphine be classified as a narcotic is based on the legal definition of "narcotic drug" in 21 U.S.C. 802(16), which includes all opiate derivatives, because buprenorphine is derived from the opiate thebaine.

I concur with these recommendations and have enclosed the Basis for Rescheduling of Buprenorphine as a Schedule V Narcotic Under the Controlled Substances Act.

The Drug Abuse Advisory Committee of the FDA Bureau of Drugs has recommended that the agonist-antagonist class of analgesic drugs (butorphanol, nalbuphine, pentazocine and buprenorphine) be monitored and periodically reviewed for changes in abuse patterns. To this end, the Department of Health and Human Services would appreciate your cooperation in reporting diversion and any other law enforcement data on this class of drugs to the Food and Drug Administration at yearly, or if possible, semi-yearly intervals.

Should you, or any of your staff, have any questions, please direct your inquiries to the

Drug Abuse Staff of the Bureau of Drugs, Food and Drug Administration.

Sincerely yours,

Edward N. Brandt, Jr., M.D.,
Assistant Secretary for Health.

Based on the scientific and medical evaluation and the recommendation of the Secretary, Department of Health and Human Services, with respect to buprenorphine, received in accordance with section 201(b) of the CSA (21 U.S.C. 811(b)), and 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 Acting Administrator by regulations of the Department of Justice (28 CFR Part 0.100), the Acting Administrator hereby proposes that paragraph (b)(1) through (b)(6) of Title 21, Code of Federal Regulations, § 1308.15 be redesignated as (c)(1) through (c)(6) and that a new paragraph (b) entitled *Narcotic drugs* be added to § 1308.15 of Title 21 of the Code of Federal Regulations (CFR) to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

§ 1308.15 Schedule V.

* * * * *

(b) *Narcotic drugs.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below:

(1) Buprenorphine..... 9064

* * * * *

All interested persons are invited to submit their comments or objections in writing regarding this proposal. If a person believes that one or more issues raised by him warrant a hearing, he should so state and summarize the reasons for his belief. Comments and objections should be submitted in quintuplicate to the Acting Administrator, Drug Enforcement Administration, 1405 I Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative.

In the event that comments or objections to this proposal raise one or more issues which the Acting Administrator finds, in his sole discretion, warrant a hearing, the Acting Administrator will publish in the **Federal Register** an order for a public hearing which will summarize the issues to be heard and set the time for the hearing that will not be less than 30 days after the date of the order.

Pursuant to Title 5, United States Code, section 605(b), the Acting Administrator certifies that the

rescheduling of buprenorphine, as proposed herein, will not have a significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). The regulatory requirements imposed on Schedule V substances are considerably less burdensome than those imposed on Schedule II substances.

In accordance with the provisions of 21 U.S.C. 811(a), this proposal to reschedule buprenorphine from Schedule II to Schedule V 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 have been exempted from the consultation requirements of Executive Order 12291 (46 FR 13193).

Dated: September 15, 1982.

Francis M. Mullen, Jr.,
Acting Administrator, Drug Enforcement Administration.

[FR Doc. 82-25845 Filed 9-17-82; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 240

[Notice No. 426; Re: Notice No. 413]

Materials and Processes for the Production and Treatment of Wine, Juice, and Distilling Material

AGENCY: Bureau of Alcohol, Tobacco and Firearms, Treasury.

ACTION: Reopening of the comment period.

SUMMARY: This notice reopens the comment period for an additional 90 calendar days on issues relating to the proposed regulatory revisions pertaining to wine treatments which were published in the *Federal Register* of June 18, 1982 (Notice No. 413, 47 FR 26399). Due to the sensitive and controversial nature of the proposed changes, the Bureau believes that an additional comment period should be given to provide an opportunity for all interested persons, especially grape growers and winemakers, to present comments.

DATE: Comments must be received on or before December 20, 1982.

ADDRESS: Comments should be addressed to: Chief, Regulations and Procedures Division, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, DC 20044-0385 (Notice No. 426).

FOR FURTHER INFORMATION CONTACT: Michael J. Breen, Rulings Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC (202-566-7632).

SUPPLEMENTARY INFORMATION:

Background

On June 18, 1982, ATF published Notice No. 413 to obtain comment on proposed regulatory changes in the listings of materials and processes authorized for use in the production and treatment of wine, juice, and distilling material. The proposed amendments update the listings of authorized materials and processes and amend the procedure for making additions and other changes. Although comments received during the original comment period generally have supported the Bureau's intent and purpose for the proposed changes, a significant number of potential commenters were unable to submit written suggestions and modifications to the proposed regulatory language due to the brevity of the comment period.

Since the proposed changes to the regulations are sensitive and controversial, ATF believes an opportunity should be given for all interested persons to submit further comments on these issues. This will ensure that all pertinent information is available to ATF before any final decision is reached. All comments previously submitted will remain a part of the record and no resubmission of comments will be necessary unless the commenter wishes to furnish additional information.

Disclosure of Comments

ATF will not recognize materials and comments as confidential. Any material which the commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comments. Comments may be disclosed to the public. The name of the person submitting comments is not exempt from disclosure.

Copies of all notices and all written comments will be available for public inspection at: ATF Reading Room, Room 4405, Federal Building, 1200 Pennsylvania Avenue, NW, Washington, DC.

Drafting Information

The author of this document is Michael J. Breen, Rulings Branch, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 240

Administrative practice and procedure, Authority delegations, Claims, Electronic funds transfers,

Excise taxes, Exports, Food additives, Fruit juices, Labeling, Liquors, Packaging and containers, Reporting requirements, Research, Scientific equipment, Spices and flavorings, Surety bonds, Transportation, Warehouses, Wine, and Vinegar.

Authority and Issuance

This notice is issued under the authority contained in Section 7805 of the Internal Revenue Code of 1954, as amended (68A Stat. 917, as amended).

Signed: August 24, 1982.

Stephen E. Higgins,
Acting Director.

Approved: September 3, 1982.

Robert E. Powis,
Acting Assistant Secretary (Enforcement and Operations).

[FR Doc. 82-25838 Filed 9-17-82; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[WH-FRL 2192-2]

Ocean Dumping; Proposed Designation of Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA today proposes to designate the existing cellar dirt disposal site located in the New York Bight as an EPA approved ocean dumping site for the dumping of cellar dirt. This action is necessary to provide an ocean dumping site for the current and future disposal of this material.

DATE: Comments must be received on or before November 4, 1982.

ADDRESSES: Send comments to: Mr. T. A. Wastler, Chief, Marine Protection Branch (WH-585), EPA, Washington, DC 20460.

The draft Environmental Impact Statement (EIS) is available for public inspection at the following locations: EPA Public Information Reference Unit (PIRU), Room 2404 (rear), 401 M Street Southwest, Washington, DC
EPA Region II Library, Room 1002, 26 Federal Plaza, New York, New York
EPA Region II Library, Woodbridge Avenue, GSA Raritan Depot, Edison, New Jersey
NOAA/RD/OMPA Northeast Office, Old Biology Building, State University of New York, Stony Brook, New York
FOR FURTHER INFORMATION CONTACT: Mr. T. A. Wastler, 202/755-0356.