

ground waters of the Basin from any surface water intake, spring, or well, or any combination of surface water intakes, springs, or wells operated as a system, exceeds 100,000 gallons per day during any 30-day period shall meter and record their withdrawals and report such withdrawals to the designated agency of the state where the withdrawals are located. Withdrawals shall be metered by means of an automatic continuous recording device, flow meter, or other method capable of measuring accurately the quantity of water withdrawn to within two percent of actual flow. Meters or other methods of measurement shall be subject to approval and inspection by the designated state agency as to installation, maintenance, calibration, and reading. Withdrawals shall at a minimum be recorded on a daily basis and reported as monthly totals annually.

(2) The following water uses and operations are exempt from the requirement of metering ground water withdrawals: farm irrigation; dewatering incidental to mining and quarrying; and dewatering incidental to construction. Persons engaged in such withdrawals in excess of 100,000 gallons per day during any 30-day period shall, in lieu of metering, record the pumping rates and the dates elapsed hours of operation of any well or pump used to withdraw water, and report such information as monthly totals annually to the designated state agency.

(3) The following are the designated state agencies for the purposes of this regulation: Delaware Department of Natural Resources and Environmental Control; New Jersey Department of Environmental Protection; New York State Department of Environmental Conservation; and Pennsylvania Department of Environmental Resources.

(4) Pursuant to Section 11.5 of the Compact, the designated state agencies shall administer and enforce programs for metering, recording, and reporting of water withdrawals, in accordance with this regulation and any applicable state regulations.

(5) This regulation shall be effective January 1, 1987.

Amendment to the Commission's Ground Water Protected Area Regulations for Southeastern Pennsylvania Relating to Ground Water Withdrawal Metering, Recording, and Reporting.

PART 430—[AMENDED]

Part 430 is proposed to be amended as follows:

1. The Authority citation for Part 430 continues to read as follows:

Authority: Pub. L. 87-328 (75 Stat. 688).

2. Existing §§ 430.19, 430.21, 430.23, 430.24, 430.25, 430.27, 430.29, and 430.31 are redesignated as §§ 430.21, 430.23, 430.25, 430.27, 430.29, 430.31, 430.33 and 430.35 respectively and the new § 430.19 is added to read as follows:

§ 430.19 Ground water withdrawal metering, recording, and reporting.

(a) Except as provided in subsection

(b), each person, firm, corporation, or other entity whose cumulative daily average withdrawal of ground water from a well or group of wells operated as a system exceeds 10,000 gallons per day during any 30-day period shall meter and record their withdrawals and report such withdrawals to the Pennsylvania Department of Environmental Resources. Withdrawals shall be metered by means of an automatic continuous recording device, flow meter, or other method capable of measuring accurately the quantity of water withdrawn to within two percent of actual flow. Meters or other methods of measurement shall be subject to approval and inspection by the Pennsylvania Department of Environmental Resources as to installation, maintenance, calibration, and reading. Withdrawals shall at a minimum, be recorded on a daily basis and reported as monthly totals annually.

(b) The following water uses and operations are exempt from the requirement of metering ground water withdrawals: farm irrigation; dewatering incidental to mining and quarrying; dewatering incidental to construction; and space heating or cooling uses that are exempt from permit requirements in Section 430.13. Except for space heating and cooling uses described herein, persons engaged in such exempt withdrawals in excess of 10,000 gallons per day during any 30-day period shall, in lieu of metering, record the pumping rates and the dates and elapsed hours of operation of any well or pump used to withdraw ground water, and report such information as monthly totals annually to the Department of Environmental Resources. Space heating and cooling uses that are exempt from permit requirements in Section 430.13 shall also be exempt from the requirement for recording and reporting.

(c) Pursuant to Section 11.5 of the Compact, the Pennsylvania Department of Environmental Resources shall administer and enforce a program for metering, recording, and reporting ground-water withdrawals in accordance with this regulation.

(d) This regulation shall be effective January 1, 1987.

Delaware River Basin Compact, 75 Stat. 688.

Susan M. Weisman,
Secretary.

February 6, 1986.

[FR Doc. 86-3115 Filed 2-12-86; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Changes in Definitions; Use of Administrative Controlled Substances Code Numbers; Addition of an Emergency Scheduling Regulation

AGENCY: Drug Enforcement Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Dangerous Drug Diversion Control Act of 1984, as part of the Comprehensive Crime Control Act of 1984 (Pub. L. 98-473), which became effective on October 12, 1984, amended portions of the Controlled Substances Act (CSA) pertaining to the schedules and scheduling of controlled substances. These amendments include a new definition of the term "isomer," a redefinition of the term "narcotic drug," and a revision of Schedule II(A)(4) to specifically list cocaine, ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives. In addition, the Administrator of the Drug Enforcement Administration (DEA) is given an emergency authority to expeditiously and temporarily place new substances of abuse into Schedule I of the CSA in order to avoid an imminent hazard to the public safety. The Dangerous Drug Diversion Control Act of 1984 also amended portions of the Controlled Substances Import and Export Act which necessitates the use of the Administration Controlled Substances Code Number by registrants. The proposed revisions to 21 CFR Part 1308 reflect these statutory changes.

DATE: Written comments and objection must be received on or before March 17, 1986.

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

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

SUPPLEMENTARY INFORMATION: The Dangerous Drug Diversion Act of 1984, as part of the Comprehensive Crime Control Act of 1984 (Pub. L. 98-473), effective October 12, 1984, represents the first major updating of the regulatory provisions of the CSA. The majority of the revisions pertain to tightening

regulatory controls in order to prevent the diversion of abusable prescription drugs from legitimate distribution channels. Several sections of this Act, however, modify those portions of the CSA regarding the scheduling and schedules of controlled substances. The proposed revisions to 21 CFR Part 1308 reflect these statutory changes in the schedules and scheduling of controlled substances.

Section 507(a) of the Dangerous Drug Diversion Act of 1984 defines the term "isomer" as it is used in section 202 of the CSA (21 U.S.C. 812). Prior to the passage of this bill the term "isomer" was defined only in 21 CFR 1308.02(c). The Dangerous Drug Diversion Act of 1984 expands the existing definition of isomer to include the optical and geometric isomers of cocaine, ecgonine and their salts and derivatives. Under this provision the levorotatory and dextrorotatory forms of cocaine, ecgonine and their derivatives and salts as well as the diastereomers, pseudococaine, pseudoecgonine, allococaine, alloecgonine, pseudoallococaine and pseudoalloecgonine and their optical isomers and salts are included in the term "isomer" as used in 21 U.S.C. 812 Schedule II(a)(4). This amendment clarifies which of the various isomers of cocaine, whether produced naturally or synthetically, are included in the term "isomer" as used in 21 U.S.C. 812 Schedule II(A)(4) and hence are controlled in Schedule II of the CSA. A revision of § 1308.02(c) of 21 CFR is proposed to reflect this change.

Section 507(b) of the Dangerous Drug Diversion Act of 1984 also modifies the existing definition of the term "narcotic drug" in the CSA. The modified definition includes poppy straw and concentrate of poppy straw which are narcotic raw materials that are imported into the United States. Cocaine, its salts, optical and geometric isomers and salts of isomers and ecgonine, its derivatives, their salts, isomers, and salts of isomers are now specifically included in the definition of "narcotic drug." Previously, cocaine and ecgonine were considered to be narcotic drugs because they were derivatives of coca leaves. Coca leaves are listed as a narcotic drug except when cocaine, ecgonine and derivatives of ecgonine or their salts have been removed. The new definition also clarifies the narcotic status of derivatives of opium and opiates under the CSA. These changes allow the language of the CSA to more clearly parallel that of the Single Convention on Narcotic Drugs, 1961 pertaining to the narcotic status of opium and opiates. An

amendment to § 1308.02 of 21 CFR adds the revised definition of "narcotic drug" to reflect the statutory change.

Section 507(c) of the Dangerous Drug Diversion Act of 1984 amends Schedule II(a)(4) to specifically list cocaine and ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives. Coupled with the amended definition of isomer which includes optical and geometric isomers of cocaine and ecgonine, the listing of these substances expands the Schedule II control of cocaine to include the isomeric forms of cocaine, ecgonine and their derivatives. Section 1308.12 Schedule II(b)(4) of 21 CFR will be revised to reflect this statutory change.

Section 508 of the Dangerous Drug Diversion Control Act of 1984 authorizes the Attorney General to temporarily and expeditiously place substances into Schedule I of the CSA if it is determined that such scheduling is necessary to avoid an imminent hazard to the public safety. Authority granted to the Attorney General by Congress in the CSA has been delegated to the Administrator of DEA by 28 CFR 0.100. The emergency scheduling provision is intended to allow the Administrator to react quickly when a new substance such as controlled substance analogs (so-called Designer Drugs) enter the illicit market and exhibit the potential of becoming a hazard to the public safety.

Under this emergency scheduling provision, the Attorney General may temporarily place a substance into Schedule I of the CSA without regard to the requirement of section 201(b) of the CSA (21 U.S.C. 811(b)) relating to the scientific and medical evaluation and scheduling recommendation of the Secretary of Health and Human Services. A notification of intention to schedule a substance under the emergency scheduling provision must be published in the **Federal Register** and transmitted to the Secretary of Health and Human Services. An emergency scheduling action may become effective after the expiration of 30 days from the date that the notification of intention to do so was published in the **Federal Register** and transmitted to the Secretary of Health and Human Services. Any comments submitted by the Secretary regarding the emergency scheduling of a substance will be considered.

The emergency scheduling provision of the CSA may be invoked only for those substances not listed in any schedule in section 202 of the CSA (21 U.S.C. 812) or if the substance has no currently accepted medical use in treatment in the United States as

defined by an approved New Drug Application or an exemption from such approval granted by the Food and Drug Administration.

Before finding that temporarily scheduling a substance in Schedule I is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider only three of the eight factors set forth in Section 201(c) of the CSA (21 U.S.C. 811(c)): (1) Its history and current pattern of abuse; (2) the scope, duration and significance of abuse; and (3) what, if any, risk there is to the public health. The Administrator is directed to consider the actual abuse, diversion and clandestine production, distribution and importation of the substance. An emergency scheduling order may be effective for one year with a possible extension for up to six months if scheduling procedures have been initiated pursuant to section 201(a) of the CSA (21 U.S.C. 811(a)). An emergency scheduling order will be terminated upon the completion of a subsequent rulemaking proceeding initiated under section 201(a) of the CSA (21 U.S.C. 811(a1)). Emergency scheduling orders, consistent with other temporary and emergency orders, are not subject to judicial review. A new section 21 CFR 1308.52 is proposed to describe the emergency scheduling process in the regulations.

Section 524 of the Diversion Control Amendments amends 21 U.S.C. 958(b) to limit the import and export of controlled substances by DEA registrants to those controlled substances specified in their registration. In order to make this determination, DEA will require registrants and applicants to use the Administration Controlled Substances Code Number which is described in 21 CFR 1308.03. An amendment to § 1308.03 is proposed to reflect this statutory change.

List of Subjects in 21 CFR Part 1308

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

Pursuant to the authority vested in the Attorney General by 21 U.S.C. 871(b) and delegated to the Administrator of the Drug Enforcement Administration by 28 CFR 0.100, the Administrator hereby proposes that 21 CFR Part 1308 be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for Part 1308 continues to read as follows:

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

2. Section 1308.02 is amended by revising paragraph (c), adding a new paragraph (e), and redesignating existing paragraphs (e) and (f) as (f) and (g) as follows:

§ 1308.02 Definitions.

(c) The term "isomer" means the optical isomer, except as used in § 1308.11(d) and § 1308.12(b)(4). As used in § 1308.11(d), the term "isomer" means the optical, positional, or geometric isomer. As used in § 1308.12(b)(4), the term "isomer" means the optical or geometric isomer.

(e) The term "narcotic drug" means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(1) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(2) Poppy straw and concentrate of poppy straw.

(3) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed.

(4) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(5) Ecgonine, its derivatives, their salts, isomers and salts of isomers.

(6) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (e) (1) through (5) of this section.

3. Section 1308.03 is amended by revising paragraph (a) to read as follows:

§ 1308.03 Administration Controlled Substances Code Number.

(a) Each controlled substance, or basic class thereof, has been assigned an "Administration Controlled Substances Code Number" for purposes of identification of the substances or class on certain Certificates of Registration issued by the Administration pursuant to §§ 1301.44 and 1311.43 of this chapter and on certain order forms issued by the Administration pursuant to § 1305.05(d) of this chapter. Applicants for procurement and/or individual

manufacturing quotas must include the appropriate code number on the application as required in §§ 1303.12(b) and 1303.22(a) of this chapter. Applicants for import or export permits must include the appropriate code number on the application as required in §§ 1312.12(a) and 1312.22(a) of this chapter. Authorized registrants who desire to import or export a controlled substance for which an import or export permit is not required must include the appropriate Administration Controlled Substances Code Number beneath or beside the name of each controlled substance listed on the DEA Form 236 (Controlled Substance Import/Export Declaration) which is executed for such importation or exportation as required in §§ 1312.18(c) and 1312.27(b) of this chapter.

4. Section 1308.12(b)(4) is revised to read as follows:

§ 1308.12 Schedule II.

(b) (4) Coca leaves and any salt, compound, derivative or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

5. A new § 1308.52 is added to read as follows:

§ 1308.52 Emergency scheduling.

Pursuant to section 201(h) of the Act (21 U.S.C. 811(h)), and without regard to the requirements of section 201(b) of the Act (21 U.S.C. 811(b)) relating to the scientific and medical evaluation of the Secretary of Health and Human Services, the Administrator may place a substance into Schedule I on a temporary basis, if he determines that such action is necessary to avoid an imminent hazard to the public safety. An order issued under this section may not be effective before the expiration of 30 days from (a) the date of publication by the Administrator of a notice in the *Federal Register* of his intention to issue such order and the grounds upon which such order is to be issued, and (b) the date the Administrator has transmitted notification to the Secretary of Health and Human Services of his intention to issue such order. An order issued under this section shall be vacated upon the

conclusion of a subsequent rulemaking proceeding initiated under section 201(a) (21 U.S.C. 811(a)) with respect to such substance or at the end of one year from the effective date of the order scheduling the substance, except that during the pendency of proceedings under section 201(a) (21 U.S.C. 811(a)) with respect to the substance, the Administrator may extend the temporary scheduling for up to six months.

The Administrator hereby certifies that this proposal will have no significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. These changes are predominantly clarifications of existing regulations. The new regulation regarding emergency scheduling applies only to clandestinely produced and harmful drugs of abuse which have no currently accepted medical use in the United States, and therefore does not impact upon the legitimate pharmaceutical industry.

Pursuant to section 3(c)(3) and 3(e)(2)(B) of Executive Order 12291, the proposed action has been submitted for review by the Office of Management and Budget, and approval of that office has been requested pursuant to the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, et seq.).

Dated: February 3, 1986.

John C. Lawn,
Administrator, Drug Enforcement
Administration.
[FR Doc. 86-3195 Filed 2-12-86; 8:45 am]

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 4

[Notice No. 581]

Grape Variety Names; Wine Labeling

Correction

In FR Doc. 86-2300 beginning on page 4392 in the issue of Tuesday, February 4, 1986, make the following corrections:

1. On page 4395, in the second column, in § 4.91, in the second column of the list, in the sixteenth line, "Emeral Riesling" should read "Emerald Riesling"; in the third column, in the first column of the list, "Rugy Cabernet" should read "Ruby Cabernet"; and in the second column of the list