

National Environmental Policy Act (21 CFR Part 25), an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(4).

For the supplement to NADA 134-930, the agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, Part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 522 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

2. Section 522.850 is amended by revising paragraph (c)(2) to read as follows:

§ 522.850 Estradiol valerate and norgestomet in combination.

* * * * *

(c) * * *

(2) *Indications for use.* For synchronization of estrus/ovulation in cycling beef cattle and non-lactating dairy heifers.

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Dated: September 12, 1986.

Marvin A. Norcross,
Associate Director for New Animal Drug Evaluation.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of 3-Methylfentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to place the narcotic substance, 3-methylfentanyl, into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). This action is based on findings made by the DEA Administrator, after a review and evaluation of the relevant data made by both DEA and the Acting Assistance Secretary of Health, that 3-methylfentanyl meets the statutory criteria for inclusion in Schedule I of the CSA. As a result of this final rule, the regulatory controls and criminal sanctions of Schedule I will be applicable to the manufacture, distribution, importation and exportation of 3-methylfentanyl.

EFFECTIVE DATE: September 22, 1986.

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

SUPPLEMENTARY INFORMATION: 3-Methylfentanyl is an extremely potent analog of the Schedule II synthetic narcotic analgesic fentanyl. Produced in clandestine laboratories, 3-methylfentanyl has been identified in the illicit drug traffic and associated with scores of overdose deaths since early 1984.

Based on the data available to him in early 1985, the DEA Administrator determined that scheduling 3-methylfentanyl in Schedule I of the CSA, at least on a temporary basis, was necessary to avoid an imminent hazard to the public safety. Therefore, in the Federal Register notice (50 FR 11690-11692) dated March 25, 1985, the DEA Administrator, pursuant to the emergency scheduling provisions of 21 U.S.C. 811(h), placed 3-methylfentanyl into Schedule I of the CSA for one year effective on April 25, 1985. The temporary scheduling of 3-methylfentanyl was extended until October 25, 1986 in a subsequent Federal Register notice (51 FR 15474-15475).

On April 24, 1986, in a notice of proposed rulemaking published in the Federal Register (51 FR 15501-15502), after an independent review by DEA and a scientific and medical evaluation by the Acting Assistant Secretary for Health of the relevant data regarding 3-methylfentanyl, the DEA Administrator proposed to permanently place 3-methylfentanyl into Schedule I of the CSA pursuant to 21 U.S.C. 811. Interested parties were given until May 27, 1986 to submit comments or objections in writing regarding this

proposal. DEA received no comments or objections nor were there any requests for a hearing.

Based upon the investigations and review conducted by DEA and upon the scientific and medical evaluation and recommendation of the Acting Assistant Secretary for Health received in accordance with 21 U.S.C. 811(c), the DEA Administrator, pursuant to the provisions of 21 U.S.C. 811 (a) and (b), finds that:

(1) 3-Methylfentanyl has a high potential for abuse;

(2) 3-Methylfentanyl has no currently accepted medical use in treatment in the United States; and

(3) 3-Methylfentanyl lacks accepted safety for use under medical supervision.

The above findings are consistent with the placement of 3-methylfentanyl into Schedule I of the CSA. The Administrator further finds that 3-methylfentanyl is an opiate as defined in 21 U.S.C. 802(18) since it has an addiction-forming and addiction-sustaining liability similar to that of morphine. Consequently, 3-methylfentanyl is a narcotic since the definition of narcotic, as stated in 21 U.S.C. 802(17)(A), includes: "Opium, opiates, derivatives of opium and opiates."

In accordance with 21 U.S.C. 811(h)(5) the emergency scheduling order for 3-methylfentanyl shall be vacated on the effective date of this final rule permanently placing 3-methylfentanyl into Schedule I of the CSA pursuant to 21 U.S.C. 811(a).

Since 3-methylfentanyl is already under temporary control in Schedule I, all regulations applicable to Schedule I narcotic substances will continue to be effective as of September 22, 1986. The current applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports 3-methylfentanyl, or who engages in research or conducts instructional activities with respect to this substance, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations.

2. *Security.* 3-Methylfentanyl must be manufactured, distributed and stored in accordance with §§ 1301.71-1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of 3-methylfentanyl must comply with the requirements of §§ 1302.03-1302.05,

1302.07 and 1302.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* All persons required to obtain quotas for 3-methylfentanyl shall submit applications pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of 3-methylfentanyl shall take an inventory pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations of all stocks of this substance on hand.

6. *Records.* All registrants required to keep records pursuant to §§ 1304.21-1304.27 of Title 21 of the Code of Federal Regulations shall maintain such records on 3-methylfentanyl.

7. *Reports.* All registrants required to submit reports pursuant to §§ 1304.34-1304.37 of Title 21 of the Code of Federal Regulations shall do so regarding 3-methylfentanyl.

8. *Order Forms.* All registrants involved in the distribution of 3-methylfentanyl must comply with the order form requirements of §§ 1305.01-1305.16 of Title 21 of the Code of Federal Regulations.

9. *Importation and Exportation.* All importation and exportation of 3-methylfentanyl shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* The Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to 3-methylfentanyl not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the placement of 3-methylfentanyl into Schedule I of the Controlled Substances Act will have no impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). This action involves the permanent control of a substance with no legitimate medical use or manufacture in the United States.

In accordance with the provisions of 21 U.S.C. 811(a), this scheduling action is a formal rulemaking "on the record after opportunity for a hearing." Such formal 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).

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), the Administrator hereby orders that 21 CFR 1308.11 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 1308.11 is amended by redesignating the existing paragraphs (b)(31) through (b)(46) as (b)(32) through (b)(47) and adding a new paragraph (b)(31) as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(31) 3-Methylfentanyl (*N*-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-*N*-phenylpropanamide), 9813

* * * * *

3. Section 1308.11 is amended by removing paragraph (g)(1) and redesignating the existing paragraphs (g)(2) through (g)(13) as (g)(1) through (g)(12).

Dated: September 15, 1986.

John C. Lawn,
Administrator, Drug Enforcement
Administration.
[FR Doc. 86-21398 Filed 9-19-86; 8:45 am]
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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 8100]

Income Tax; Taxable Years Beginning After December 31, 1953; OMB Control Numbers Under the Paperwork Reduction Act; Cooperative Hospital Service Organizations

Correction

§ 1.501(e)-1 [Corrected]

In FR Doc. 86-19940 beginning on page 31613 in the issue of Thursday, September 4, 1986, make the following correction: On page 31615, in § 1.501(e)-1(b)(4), in the third column, in the sixteenth line from the bottom, "512(b)(A)(ii)" should read "512(b)(3)(A)(ii)".

BILLING CODE 1505-01-M

26 CFR Parts 46 and 602

[T.D. 8102]

Excise Tax Imposed on the Issuer of Registration-Required Obligation Not in Registered Form

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the excise tax imposed on the issuer or registration-required obligations which are not issued in registered form. This action is necessary because of changes to the applicable law made by the Tax Equity and Fiscal Responsibility Act of 1982. The regulations affect issuers of obligations and provide them with the guidance needed to comply with the law.

DATES: The regulations are generally effective for registration-required obligations not in registered form that are issued after December 31, 1982.

FOR FURTHER INFORMATION CONTACT: Timothy J. McKenna of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224 (Attention: CC:LR:T) (202-566-4336, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

On August 22, 1984, the Federal Register published proposed amendments to the Excise Tax Regulations (26 CFR Part 46) under section 4701 of the Internal Revenue Code of 1954 (49 FR 33285). These amendments were proposed to conform the regulations to section 310(b)(4) of the Tax Equity and Fiscal Responsibility Act of 1982 (the Act) (Pub. L. 97-248, 96 Stat. 597). No comments were received. A public hearing was not requested. Accordingly, the proposed amendments are adopted as revised by this Treasury decision.

In General

Section 4701(a) provides that a tax is imposed on any person who issues a registration-required obligation which is not in registered form. The amount of the tax is one percent of the principal amount multiplied by the number of years (including portions thereof) from the date of issuance to the date of maturity. The terms "registration-required obligation" and "registered form" are defined in section 4701(b) as having the same meaning as when used