regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in CFR Part 97

Approaches, Standard instrument, Incorporation by reference.

Issued in Washington, DC on December 25, 1987.

Robert L. Goodrich,
Director of Flight Standards.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Part 97 of the Federal Aviation Regulations (14 CFR Part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 G.M.T. on the dates specified, as follows:

PART 97—(AMENDED)

1. The authority citation for Part 97 continues to read as follows:

Authority: 49 U.S.C. 1348, 1354(a), 1421, and 1510; 49 U.S.C. 106(g) [revised, Pub. L. 97-449, January 12, 1983; and 14 CFR 11.49(h)(2)].

§ 97.23 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR/LOC or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMILS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SLAIPS; § 97.33 RNAV SLAIPS; and § 97.35 COPPER SLAIPS, identified as follows:

[Effective March 10, 1988]

Santa Ana, CA—John Wayne Airport-Orange County, LOC BC RWY 11, Amdt. 10
Santa Ana, CA—John Wayne Airport-Orange County, NDB RWY 11, Amdt. 1
Santa Ana, CA—John Wayne Airport-Orange County, ILS RWY 19R, Amdt. 11
Charles City, IA—Charles City Muni, NDB RWY 12, Amdt. 9
Charles City, IA—Charles City Muni, NDB RWY 30, Amdt. 1
Elmira, NY—Elmira/Corning Regional, NDB RWY 24, Amdt. 12
Elmira, NY—Elmira/Corning Regional, ILS RWY 24, Amdt. 14
Newburgh, NY—Stewart Intl, VOR or TACAN RWY 27, Amdt. 3
Newburgh, NY—Stewart Intl, NDB RWY 19, NDB RWY 9, Amdt. 4
Newburgh, NY—Stewart Intl, NDB RWY 19, Amdt. 2
Newburgh, NY—Stewart Intl, RNAV RWY 27, Amdt. 1
Poughkeepsie, NY—Dutchess County, ILS RWY 6, Amdt. 5
Poughkeepsie, NY—Dutchess County, RNAV RWY 6, Amdt. 5

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of Beta-Hydroxy-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, beta-hydroxy-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 by both DEA and the Assistant Secretary for Health, that beta-hydroxy-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 are applicable to the manufacture, distribution, importation, exportation and possession of beta-hydroxy-3-methylfentanyl.


FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 639-1386.

SUPPLEMENTARY INFORMATION: On November 28, 1986, in a notice of proposed rulemaking published in the Federal Register (51 FR 49025), after a review of relevant data, the DEA Administrator proposed to place acetyl-alpha-methylfentanyl, acetyl-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiophenylfentanyl into Schedule I of the CSA pursuant to 21 U.S.C. 811(a). This proposed rule provided the opportunity for interested parties to submit comments or objections regarding the proposed scheduling actions. DEA received no comments or objections nor were there any requests for hearings.

After receiving and taking into consideration the scientific and medical evaluation and scheduling recommendations of the Secretary of Health and Human Services regarding acetyl-alpha-methylfentanyl, acetyl-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiophenylfentanyl, the DEA Administrator issued a final rule on May 29, 1987 placing these substances into Schedule I of the CSA (52 FR 20070). The temporary control of these substances plus beta-hydroxy-3-methylfentanyl in Schedule I of the CSA pursuant to 21 U.S.C. 811(h) expired on May 29, 1987. By letter dated October 27, 1987, the DEA Administrator received the scientific and medical evaluation and scheduling recommendation for beta-hydroxy-3-methylfentanyl from the Assistant Secretary for Health, delegate of the Secretary of the Department of Health and Human Services. He recommended that beta-hydroxy-3-methylfentanyl be placed into Schedule I of the CSA.

Beta-hydroxy-3-methylfentanyl is an extremely potent analog of the Schedule II synthetic narcotic analgesic fentanyl. It behaves as a morphine-like substance in rodent antinociceptive tests. Further this fentanyl analog is a substrate completely for morphine when administered to morphine dependent withdrawn monkeys. The primate single-dose suppression potency is 6000
times that of morphine. Beta-hydroxy-3-methylfentanyl has been produced in clandestine laboratories and identified in drug evidence submissions to forensic laboratories. It is likely some of the more than 500 overdose deaths associated with fentanyl analog use involved beta-hydroxy-3-methylfentanyl.

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

(1) Beta-hydroxy-3-methylfentanyl has a high potential for abuse;

(2) Beta-hydroxy-3-methylfentanyl has no currently accepted medical use in treatment in the United States, and

(3) Beta-hydroxy-3-methylfentanyl lacks accepted safety for use under medical supervision.

The above findings are consistent with the placement of beta-hydroxy-3-methylfentanyl into Schedule I of the CSA. The Administrator further finds that beta-hydroxy-3-methylfentanyl is an opiate as defined in 21 U.S.C. 802(18) since it has an addiction-forming and an addiction-sustaining liability similar to that of morphine. Consequently, beta-hydroxy-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,"

All regulations applicable to Schedule I narcotic substances are effective as of January 8, 1988, with respect to beta-hydroxy-3-methylfentanyl. The current applicable regulations are as follows:

1. Registration. Any person who manufactures, distributes, delivers, imports or exports beta-hydroxy-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. Beta-hydroxy-3-methylfentanyl must be manufactured, distributed and stored in accordance with §1300.71-1300.79 of Title 21 of the Code of Federal Regulations.

3. Labeling and packaging. All labels and labeling for commercial containers of beta-hydroxy-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 beta-hydroxy-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 beta-hydroxy-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 beta-hydroxy-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 beta-hydroxy-3-methylfentanyl.

8. Order forms. All registrants involved in the distribution of beta-hydroxy-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 beta-hydroxy-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 beta-hydroxy-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 beta-hydroxy-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 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 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:


2. Section 1308.11 is amended by redesignating existing paragraphs (b)(12) through (b)(54) as (b)(13) through (b)(65) and adding a new paragraph (b)(12) as follows:

§1308.11 Schedule I

(b) * * * * *

(12) Beta-hydroxy-3-methylfentanyl

[other name: N-[1,2-dihydroxy-2-phenethyl]-3-methyl-4-piperidinyl]-N-phenylpropanamide] 9630 * * * * *

§1308.11 [AMENDED]

3. Section 1308.11 is further amended by removing paragraph (g)(2) and redesignating existing paragraphs (g)(3) through (g)(6) as (g)(2) through (g)(5).


John C. Lawn,
Administrator, Drug Enforcement Administration.

[FR Doc. 88-279 Filed 1-7-88; 8:45 am]
BILLING CODE 4410-09-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

(FRL-3313-5; KY-047)

Approval and Promulgation of Implementation Plans; Kentucky: 401 KAR 61:140, Existing By-Product Coke Manufacturing Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA today approves a revision to 401 KAR 61:140, Existing by-product coke manufacturing plants, submitted by Kentucky on September 19, 1986. This revision changes the test method for measuring total dissolved