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 520 is amended as follows:

## PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 520 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 520.1236 is amended by revising paragraph (a) to read as follows:

**§ 520.1236 Lenperone tablets.**

(a) *Specifications.* Each tablet contains 5, 10, or 25 milligrams of lenperone hydrochloride.

* * * * *

Dated: November 18, 1986.

**Marvin A. Norcross,**

*Associate Director for New Animal Drug Evaluation.*

[FR Doc. 86-26598 Filed 11-25-86; 8:45 am]

BILLING CODE 4160-01-M

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### 21 CFR Part 1308

### Schedules of Controlled Substances; Extension of Temporary Placement of Acetyl-alpha-methylfentanyl, Alpha-methylthiofentanyl, Beta-hydroxyfentanyl, Beta-hydroxy-3-methylfentanyl, 3-Methylthiofentanyl and Thiofentanyl 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 extend the temporary scheduling of the narcotic substances, acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). The temporary scheduling of these six substances is due to expire on November 29, 1986. This notice will extend the temporary scheduling of the six fentanyl analogs for six months or until rulemaking proceedings pursuant to 21 U.S.C. 811(a) are completed, whichever occurs first.

**EFFECTIVE DATE:** November 29, 1986.

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

**SUPPLEMENTARY INFORMATION:** On October 29, 1985, the Administrator of the Drug Enforcement Administration issued a final rule in the **Federal Register** (50 FR 43698-702) amending § 1308.11(g) of Title 21 of the Code of Federal Regulations to temporarily place six fentanyl analogs into Schedule I of the Controlled Substances Act pursuant to the emergency scheduling provisions of 21 U.S.C. 811(h). The six fentanyl analogs are:

(1) acetyl-alpha-methylfentanyl (*N*-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-*N*-phenylacetamide)

(2) alpha-methylfentanyl (*N*-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-*N*-phenylpropanamide)

(3) beta-hydroxyfentanyl (*N*-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-*N*-phenylpropanamide)

(4) beta-hydroxy-3-methylfentanyl (*N*-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-*N*-phenylpropanamide)

(5) 3-methylthiofentanyl (*N*-[1-(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-*N*-phenylpropanamide)

(6) thiofentanyl (*N*-phenyl-*N*-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide)

The final rule which became effective on November 29, 1985 was based on findings by the Administrator that the emergency scheduling of the above referenced six fentanyl analogs was necessary to avoid an imminent hazard to the public safety. Section 201(h)(2) of the CSA (21 U.S.C. 811(h)(2)) requires that the emergency scheduling of a substance expires at the end of one year from the effective date of the order. However, during the pendency of proceedings under 21 U.S.C. 811(a)(1) with respect to the substance, temporary scheduling of that substance may be extended for up to six months. Proceedings for the scheduling of a substance under 21 U.S.C. 811(a) may be initiated by the Attorney General (delegated to the Administrator of DEA pursuant to 28 CFR 0.100) on his own motion, at the request of the Secretary of the Department of Health and Human Services, or on the petition of any interested party. Such proceedings regarding the six fentanyl analogs have been initiated by the Administrator.

Therefore, the temporary scheduling of acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl which is due to expire on November 29, 1986, may be extended until May 29, 1987, or until proceedings initiated in accordance with 21 U.S.C. 811(a) are completed; whichever occurs first.

Pursuant to 21 U.S.C. 811(h)(2) the Administrator hereby orders that the temporary scheduling of acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl be extended until May 29, 1987 or until the conclusion of scheduling proceedings initiated in accordance with 21 U.S.C. 811(a); whichever occurs first.

Pursuant to Title 5, United States Code, section 605(b), the Administrator certifies that the extended scheduling of acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl in 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). The substances, acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl have no legitimate use or manufacturer in the United States.

It has been determined that the extension of the temporary placement of acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylthiofentanyl and thiofentanyl in Schedule I of the CSA under the emergency scheduling provision is a statutory exception to the 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.

Dated: November 21, 1986.

**John C. Lawn,**

*Administrator, Drug Enforcement Administration.*

[FR Doc. 86-26643 Filed 11-25-86; 8:45 am]

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