

is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, Part 178 is amended as follows:

#### PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR Part 178 continues to read as follows:

**Authority:** Secs. 201(s), 409, 72 Stat, 1784-1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. In § 178.2010 paragraph (b) is amended in the entry "*N,N'*-Hexamethylenebis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamamide)" by adding new entries 6 and 7 to read as follows:

#### § 178.2010 Antioxidants and/or stabilizers for polymers.

\* \* \* \* \*

(b) \* \* \*

Substances	Limitations
<i>N,N'</i> -Hexamethylenebis(3,5-di- <i>tert</i> -butyl-4-hydroxyhydrocinnamamide) (CAS Reg. No. 23128-74-7).	For use only: * * * 6. At levels not to exceed 0.5 percent by weight of polyoxymethylene copolymer complying with § 177.2470 of this chapter. 7. At levels not to exceed 0.5 percent by weight of polyoxymethylene homopolymer complying with § 177.2480 of this chapter.

Dated: May 18, 1987.

Richard J. Ronk,  
Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-12227 Filed 5-28-87; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

#### Schedules of Controlled Substances; Placement of Acetyl-Alpha-Methylfentanyl, Alpha-Methylthiofentanyl, Beta-Hydroxyfentanyl, 3-Methylthiofentanyl, Para-Fluorofentanyl 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 place the narcotic substances, acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl 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 acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl meet 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, exportation and possession of the six referenced fentanyl analogs.

**EFFECTIVE DATE:** May 29, 1987.

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

**SUPPLEMENTARY INFORMATION:** Acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl are potent analogs of the Schedule II

synthetic narcotic analgesic fentanyl. Each of these fentanyl analogs behaves as a typical morphine-like compound in rodent antinociceptive tests. Further, each analog substitutes completely for morphine when administered to morphine dependent withdrawn monkeys. The six fentanyl analogs have been produced in clandestine laboratories, identified in drug evidence submissions and associated with a number of overdose deaths.

Acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl are temporarily controlled in Schedule I of the CSA pursuant to the emergency scheduling provisions of 21 U.S.C. 811(h) (51 FR 4722, 50 FR 43698). The temporary scheduling of para-fluorofentanyl expires on September 10, 1987 (52 FR 7270) and the temporary scheduling of the other five fentanyl analogs expires on May 29, 1987 (51 FR 42834).

On November 28, 1986, in a notice of proposed rulemaking published in the *Federal Register* (51 FR 43025), after a review of the relevant data, the DEA Administrator proposed to place acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl and thiofentanyl into Schedule I of the CSA pursuant to 21 U.S.C. 811(a). Likewise, on March 10, 1987, the DEA Administrator proposed to place para-fluorofentanyl into Schedule I of the CSA (52 FR 7280). Both proposed rules provided for the submission of comments or objections regarding the proposals by any interested parties. DEA received no comments or objections nor were there any requests for hearings.

In both proposed rules, the DEA Administrator stated that before issuing final rules in these matters, he would take into consideration the scientific and medical evaluations and scheduling recommendations of the Secretary of the Department of Health and Human Services in accordance with 21 U.S.C. 811(b). Scientific and medical evaluations and scheduling recommendations have been received from the Assistant Secretary for Health, Department of Health and Human Services for acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl. Based upon the investigations and reviews conducted by DEA and upon the scientific and medical evaluations and recommendations of the Assistant Secretary for Health 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) Acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl each has a potential for abuse;

(2) Acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl each has no currently accepted medical use in treatment in the United States, and

(3) Acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl each lacks accepted safety for use under medical supervision.

The above findings are consistent with the placement of acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl into Schedule I of the CSA. The Administrator further finds that acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl and opiates as defined in 21 U.S.C. 802(18) since they have an addiction-forming and an addiction-sustaining liability similar to that of morphine. Consequently, acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl are narcotics 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 orders for acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl shall be vacated on the effective date of this final rule, placing the above named fentanyl analogs into Schedule I of the CSA pursuant to 21 U.S.C. 811(a).

Since acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl are already under temporary control in Schedule I, all regulations applicable to Schedule I narcotic substances will continue to be effective as of [May 29, 1987]. The current applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers,

imports or exports acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl or thiofentanyl, or who engages in research or conducts instructional activities with respect to these substances, 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.* Acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl 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 acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl must comply with the requirements of §§ 1302.03-1302.05, 1302.07 and 132.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* All persons required to obtain quotas for acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl or thiofentanyl, shall submit applications pursuant to §§ 1303.12 and 1302.22 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl or thiofentanyl shall take an inventory pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations of all stocks of these substances 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 acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl.

7. *Records.* All registrants required to submit records pursuant to §§ 1304.34-1304.37 of Title 21 of the Code of Federal Regulations shall do so regarding acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl.

8. *Order-Forms.* All registrants involved in the distribution of acetyl-

alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl or thiofentanyl 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 acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl 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 acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl, or thiofentanyl 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 acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, beta-hydroxyfentanyl, 3-methylthiofentanyl, para-fluorofentanyl and thiofentanyl 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 six substances 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. In § 1308.11, the introductory text of paragraph (b) is revised to read as follows:

\* \* \* \* \*

§ 1308.11 Schedule I.

\* \* \* \* \*

(b) *Opiates*. Unless specifically excepted or unless listed in another schedule, any of the following 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 (for purposes of paragraph (b)(34) only, the term isomer includes the optical and geometric isomers):

\* \* \* \* \*

3. Section 1308.11 is further amended by redesignating paragraphs (b)(1) through (b)(6) as (b)(2) through (b)(7), paragraphs (b)(7) and (b)(8) as (b)(9) and (b)(10), paragraphs (b)(9) through (b)(30) as (b)(12) through (b)(33), paragraphs (b)(31) through (b)(36) as (b)(35) through (b)(40), paragraphs (b)(37) through (b)(46) as (b)(42) through (b)(51) and paragraphs (b)(47) and (b)(48) as (b)(53) and (b)(54) and by adding new paragraphs (b)(1), (b)(8), (b)(11), (b)(34), (b)(41) and (b)(52) as follows:

§ 1308.11 Schedule I

\* \* \* \* \*

(b) \* \* \*

(1) Acetyl-alpha-methylfentanyl (*N*-[1-(1-methyl-2-phenethyl)-4-piperidiny]-*N*-phenylpropanamide)—9815

\* \* \* \* \*

(8) Alpha-methylthiofentanyl (*N*-[1-methyl-2-(2-thienyl)ethyl-4-piperidiny]-*N*-phenylpropanamide)—9832

\* \* \* \* \*

(11) Beta-hydroxyfentanyl (*N*-[1-(2-hydroxy-2-phenethyl)-4-piperidiny]-*N*-phenylpropanamide)—9830

\* \* \* \* \*

(34) 3-methylthiofentanyl (*N*-[1-(3-methyl-1-(2-thienyl)ethyl-4-piperidiny]-*N*-phenylpropanamide)—9833

(41) Para-fluorofentanyl (*N*-[4-fluorophenyl]-*N*-[1-(2-phenethyl)-4-piperidiny]propanamide)—9812

\* \* \* \* \*

(52) Thiofentanyl (*N*-phenyl-*N*-[1-(2-thienyl)ethyl-4-piperidiny]-propanamide)—9835

\* \* \* \* \*

§ 1308.11 [Amended]

4. Section 1308.11 is further amended by removing paragraphs (g)(1), (g)(2),

(g)(4), (g)(6), (g)(8) and (g)(9) and redesignating existing paragraph (g)(3) as (g)(1), existing paragraph (g)(5) as (g)(2), and existing paragraph (g)(7) as (g)(3).

Dated: May 27, 1987.

John C. Lawn,  
Administrator, Drug Enforcement  
Administration.

[FR Doc. 87-12417 Filed 5-28-87; 8:45 am]

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**DEPARTMENT OF LABOR**

**Occupational Safety and Health  
Administration**

**29 CFR Part 1956**

**New York State Plan for State and  
Local Government Employees**

**AGENCY:** Department of Labor,  
Occupational Safety and Health  
Administration (OSHA).

**ACTION:** Approval of supplements to the New York State public employee only State plan: Change in developmental schedule; change in staffing plan; completion of a developmental step.

**SUMMARY:** This notice approves the supplement revising the approved New York development schedule in 29 CFR 1956.51 (the supplement amends the dates in the developmental schedule for steps (b), (g) and (h) and changes step (1) to reflect New York's intention to implement a public sector consultation program through written procedures rather than promulgation of regulations); approves the supplement for a State initiated change reassigning two positions from Industrial Hygiene Consultation to Industrial Hygiene Enforcement; and, approves completion of a developmental step (adoption of all OSHA standards promulgated as of July 1, 1983 (within three months after plan approval)).

**EFFECTIVE DATE:** May 29, 1987.

**FOR FURTHER INFORMATION CONTACT:** James Foster, Director, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, 200 Constitution Avenue NW., Room N3647, Washington, DC 20210, Telephone (202) 523-8148.

**SUPPLEMENTARY INFORMATION:**

**A. Background**

Part 1953 of Title 29, Code of Federal Regulations, prescribes procedures under section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the Act) by which the Occupational Safety and Health

Administration will review and approve standards promulgated pursuant to a State plan which has been approved in accordance with section 18(c) of the Act and Part 1956.

On June 1, 1984, notice was published in the Federal Register (49 FR 22994), of the initial approval of the New York plan applicable only to public employees and adoption of Subpart F of Part 1956 containing the approval decision and description of the plan, including the developmental schedule in § 1956.51.

**B. Description of Supplements**

**1. Developmental Schedule**

The State submitted a revised developmental schedule on April 1, 1986 which amends the dates of completion for steps (b) inspections, Citations; (g) Non-discrimination Procedures; and, (h) Review Procedures; and changes step (1) to reflect New York's intention to implement its public sector consultation program through written procedures rather than promulgation of regulations. (The New York State Labor Department's Division of Safety and Health since 1975 also has had an on-site consultation program in the private sector, administered separately from its public employee State plan under section 7(c)(1) of the Act). Completion of developmental steps (b), (g) and (h), as amended, and implementation and completion of step (1), as amended, will be accomplished within the three year period as provided by OSHA Regulation at 29 CFR 1956.2(b). The State's revision of the dates of completion for the three developmental steps does not diminish its responsibility to complete all developmental steps within the three year period as provided in OSHA Regulation at 29 CFR 1956.2(b). Further, New York's intention to implement an on-site consultation program through written procedures rather than promulgation of regulations provides for the establishment, implementation and administration of an effective voluntary compliance program and does not diminish the State's ability to provide on-site consultation services to public employers as a component of its approved State plan.

**2. Change in Staffing Plan**

On September 3, 1986, the State submitted a supplement providing for the reassignment of two positions from Industrial Hygiene Consultation to Industrial Hygiene Enforcement. One (1) Industrial Hygiene Consultation position