Drafting Information
The principal author of this document was Larry L. Burton, Regulations Control Branch, Office of Regulations and
Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

Amendment to the Regulations
Part 178, Customs Regulations (19 CFR Part 178), is amended as set forth below:

PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

1. The authority citation for Part 178 continues to read as follows:
   Authority: 5 U.S.C. 301, 19 U.S.C. 1624, 44
   U.S.C. 3501 et seq.

2. Section 178.2 is amended by inserting, in proper numerical order, the following entry:

   § 178.2 Listing of OMB control numbers.

   19 CFR section   Description                        OMB control No.
   § 6.12a... Customs security areas in international airports. 1515-0152

B. James Fritz,
Director, Regulations Control and Disclosure
Law Division.

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DEPARTMENT OF JUSTICE
Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances;
Temporary Placement of Para-
Fluorofentanyl Into Schedule I of the
Controlled Substances Act

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this notice to temporarily place para-fluorofentanyl into Schedule I of the Controlled Substances Act (CSA) pursuant to the emergency scheduling provision of the CSA. This action is based on a finding that the scheduling of this substance in Schedule I is necessary to avoid an imminent hazard to the public safety. This action will impose the criminal sanctions and regulatory controls of Schedule I on the manufacturing, distribution and possession of para-fluorofentanyl.

EFFECTIVE DATE: On March 10, 1986, para-fluorofentanyl will be subject to Schedule I control.


SUPPLEMENTAL INFORMATION:
List of Subjects in 21 CFR Part 1308

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

The Comprehensive Crime Control Act of 1984 (Pub. L. 99-473), which was signed into law on October 12, 1984, amended section 201 of the Controlled Substances Act (CSA) [21 U.S.C. 811] to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA if he finds that such action is necessary to avoid an imminent hazard to the public safety. A substance may be scheduled under the emergency provision of the CSA if that substance is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no approval or exemption in effect under 21 U.S.C. 355 for the substance. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (28 CFR 0.100[b]). In making a finding of an imminent hazard to the public safety, the Attorney General is required to consider only those factors set forth in paragraphs (a) the history and current pattern of abuse, (b) the scope, duration and significance of abuse, and (c) what, if any, risk there is to the public health of section 201(c) of the CSA [21 U.S.C. 811(c)].

House Report 98-835 which accompanied Pub. L. 98-473 states that "This new procedure [emergency scheduling] is intended by the Committee to apply to what has been called 'designer drugs', new chemical analogs of existing controlled substances, or other new substances, which have a psychodelic, stimulant or depressant effect and have a high potential for abuse." Para-fluorofentanyl is an analog of fentanyl, a Schedule II synthetic narcotic analgesic, and as such is the type of substance which Congress intended to subject to the emergency scheduling authority as an imminent hazard to the public safety. A series of analogs of the Schedule II narcotic analgesic, fentanyl, have been clandestinely produced, distributed and abused primarily in California since late 1979. The first of these analogs identified was alpha-methylfentanyl, sold on the street as "China White" or "synthetic heroin." Alpha-methylfentanyl was associated with over 20 narcotic overdose deaths during the period 1980-1982. Using the traditional scheduling process pursuant to section 201(a) of the CSA [21 U.S.C. 811(a)], DEA placed alpha-methylfentanyl into Schedule I of the CSA effective September 22, 1981 (46 FR 46799). Since the control of alpha-methylfentanyl, DEA laboratories have identified other fentanyl analogs clandestinely produced and distributed in California. DEA used its emergency scheduling authority for the first time when 3-methyl-fentanyl, a particularly potent fentanyl analog, was temporarily placed into Schedule I of the CSA effective April 25, 1985 (50 FR 11690). Subsequently, after their identification in the illicit drug traffic by DEA laboratories, the substances, acetyl-alpha-methylfentanyl, alpha-methylthiofentanyl, benzylfentanyl, beta-hydroxyfentanyl, beta-hydroxy-3-methylfentanyl, 3-methylfentanyl, thienylfentanyl and tiophenylfentanyl were temporarily placed into Schedule I effective November 29, 1985 pursuant to the emergency scheduling provision of the CSA (50 FR 43698-702). Yet another fentanyl analog, para-fluorofentanyl, has been identified in submissions to a DEA laboratory.

Chemically, para-fluorofentanyl is N-[1-phenylethyl]-4-piperidyl]N-[4-fluorophenyl]propanamide. Para-fluorofentanyl behaves as a typical morphine-like compound in several pharmacological tests in the mouse and rat. It has a 50-minute duration of analgesic action and it is estimated to be about 100 times as potent as an analgesic as morphine. Para-fluorofentanyl substitutes completely for morphine in morphine-dependent monkeys at several doses.

DEA laboratories have identified para-fluorofentanyl in drug evidence submissions from the East Coast and West Coast. Para-fluorofentanyl was first identified by a DEA laboratory in a two-ounce submission from Los Angeles, California in 1981. Since the fall of 1985 DEA laboratories have identified substantial quantities of para-fluorofentanyl in several exhibits associated with a clandestine laboratory producing this substance in Delaware.

Para-fluorofentanyl's morphine-like pharmacological profile and high potency make it likely that it will be associated with the same type of health hazards as other fentanyl analogs. Since January 1984 there have been at least 80 overdose deaths associated with
fentanyl analogs. Due to the difficulty in detecting the minute quantities of fentanyl analogs found in body fluids, it is likely that some injuries and deaths associated with these substances go unreported.

There is no accepted medical use for or commercial manufacturer of para-fluorofentanyl. The use of clandestinely produced narcotic substances poses greater health and safety risks than those attendant to the use of traditional narcotics. The identity, purity and concentration of the active ingredients in most cases are unknown or at best inconsistent. The relatively high potency of para-fluorofentanyl (100 times morphine) necessitates very small doses. Mixing the active ingredients with diluents to obtain appropriate and uniform doses is extremely difficult. Thus, there is a high risk of overdose.

The incidence of fentanyl analog use among narcotic addicts in California has been estimated at 10 to 20 percent. Fentanyl analogs are primarily administered intravenously by narcotic addicts. The pattern of abuse of fentanyl analogs parallels that of heroin and other narcotics.

The above data show that the production, distribution and use of fentanyl analogs continue to pose a very serious hazard to the public safety, particularly in California. With the identification of substantial quantities of para-fluorofentanyl in forensic laboratory submissions from Delaware, it appears that the high potential for the spread of fentanyl analogs to areas outside of California has been realized. Although para-fluorofentanyl has not been specifically associated with injuries or deaths at this time, it is likely to produce the same health and safety risks as those associated with the use of other potent fentanyl analogs.

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h) and 28 CFR 0.100), the Administrator of DEA has considered the following factors relative to making a determination of whether para-fluorofentanyl poses an imminent hazard to the public safety:

(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.

Based on a consideration of these factors and other relevant information, the Administrator, pursuant to section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, finds that scheduling para-fluorofentanyl in Schedule I of the CSA, at least on a temporary basis, is necessary to avoid an imminent hazard to the public safety.

As required by section 201(b)(4) of the CSA (21 U.S.C. 811(b)(4)), the Administrator has notified the Secretary of the Department of Health and Human Services of his intention to temporarily place para-fluorofentanyl into Schedule I of the CSA. Comments submitted by the Secretary in response to this notification, including whether there is an exemption or approval in effect for para-fluorofentanyl under the Federal Food, Drug and Cosmetic Act, shall be taken into consideration by the Administrator before the notice becomes effective.

Pursuant to the provisions of section 201(h) of the CSA (21 U.S.C. 811(h) and 28 CFR 0.100, the Administrator hereby orders that on March 10, 1986, N-[1-(2-phenylethyl)-4-piperidyl]-N-[4-(fluorophenyl)propanamide (para-fluorofentanyl), its optical isomers, salts and salts of isomers be placed into Schedule I of the CSA (21 U.S.C. 801 et seq.) unless the Administrator gives notice in the Federal Register that this order is rescinded prior to March 10, 1986.

PART 1308—(AMENDED)

For the reasons set forth above, 21 CFR 1308.11(g) is amended as follows:

1. The authority citation for 21 CFR Part 1308 continues to read as follows:


2. Section 1308.11(g)(13) is added to read as follows:

§1308.11 Schedule I.

(13) N-[1-(2-phenylethyl)-4-piperidyl]-N-(4-fluorophenyl)propanamide (para-fluorofentanyl), its optical isomers, salts and salts of isomers

The temporary placement of para-fluorofentanyl into Schedule I, pursuant to section 201(h) of the CSA (21 U.S.C. 811(h)), will expire at the end of one year from the effective date of this order. If a rulemaking proceeding to schedule para-fluorofentanyl under the CSA has been initiated pursuant to section 201(a) of the CSA (21 U.S.C. 811(a)) and is pending, the temporary scheduling of that substance may be extended for up to six months.

This action is not a formal rulemaking procedure as set forth in the Administrative Procedures Act (5 U.S.C. 551-559) and the opportunity for a hearing on the record is not required. Nevertheless, the Administrator affords the opportunity for comments to be submitted concerning this matter.

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

All regulations and criminal sanctions applicable to Schedule I substances are effective on March 10, 1986, with respect to para-fluorofentanyl. However, individuals registered with DEA in accordance with Part 1301 or 1311 of Title 21 of the Code of Federal Regulations and who currently possess para-fluorofentanyl may continue to do so pending DEA's receipt of an amended registration no later than April 8, 1986.

1. Registration. Any person who manufactures, distributes, delivers, imports or exports para-fluorofentanyl 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.


3. Labeling and Packaging. All labels and labeling for commercial containers of para-fluorofentanyl 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 para-fluorofentanyl 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 para-fluorofentanyl 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 do so regarding para-fluorofentanyl.

7. Reports. All registrants required to submit reports pursuant to §§ 1304.37-1304.41 of Title 21 of the Code of Federal Regulations shall do so regarding para-fluorofentanyl.

8. Order Forms. All registrants involved in the distribution of para-fluorofentanyl shall 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 para-fluorofentanyl shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

10. Criminal Liability. Any activity with respect to para-fluorofentanyl not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring after March 10, 1986, is unlawful.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the temporary placement of para-fluorofentanyl 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 temporary control of substances with no legitimate medical use or manufacture in the United States.

It has been determined that the temporary placement of para-fluorofentanyl in Schedule I of the CSA under the emergency scheduling provision is a statutory exception to the requirements of Executive Order 12291 (48 FR 13103).


John C. Lawn, Administrator.

[FR Doc. 86–2721 Filed 2–6–86; 8:45 am]

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 916

Director's Findings on the Status of Kansas' Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule.

SUMMARY: On January 21, 1981, the State of Kansas received conditional approval of its permanent regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). All six conditions were removed on April 14, 1982, and full approval was granted. On March 11, 1983, the Director, OSM, notified the Governor of Kansas that OSM had reason to believe that serious problems existed and were adversely affecting the implementation of Kansas' approved regulatory program. After a public hearing and opportunity for public comment, the Director finds that while Kansas was experiencing some difficulty in adequately implementing certain aspects of its approved program, corrective measures have been initiated which will ensure that the Kansas program is implemented in accordance with the State program as approved by the Secretary of the Interior. The action initiated under the provisions of 30 CFR Part 733 is now being terminated. The Director, OSM, will continue to provide the State with assistance and guidance as necessary to ensure that the Kansas permanent regulatory program continues to be implemented as approved by the Secretary. OSM will monitor the State's actions through its ongoing oversight program.

This notice sets forth the Director's detailed findings regarding this action and the status of corrective actions initiated by the State of Kansas.

EFFECTIVE DATE: March 10, 1986.

ADDRESSES: Copies of the Director's decision and the Administrative Record documents referenced in this notice are available for public inspection and copying during regular business hours at:

Office of Surface Mining, Room 5124, 1100 "L" Street, NW., Washington, DC 20240; Telephone: (202) 343–4855.

Office of Surface Mining, Kansas City Field Office, Room 502, 1103 Grand Avenue, Kansas City, Missouri 64106; Telephone: (816) 374–5527.

Mineral Land Conservation and Reclamation Board, 107 West 11th Street, Pittsburg, Kansas; Telephone: (316) 231–8540.

FOR FURTHER INFORMATION CONTACT:

Raymond Lowrie, Assistant Director, Western Field Operations, Office of Surface Mining, Suite 702, Executive Tower Inn, 1405 Curtis Street, Denver, Colorado 80202; Telephone: (303) 844–2459

William Kovacic, Director, Kansas City Field Office, Office of Surface Mining, Room 502, 1103 Grand Avenue, Kansas City, Missouri 64106; Telephone: (816) 374–5527.

SUPPLEMENTARY INFORMATION:

I. Background

On January 21, 1981, the Secretary of the Interior conditionally approved the Kansas program to administer and enforce the permanent regulatory program under SMCRA. All six of the conditions were removed on April 14, 1982.

On March 11, 1983, the Director, OSM, notified the Governor of Kansas that he had reason to believe that the State, through the Mined Land Conservation and Reclamation Board (MLCRB or the Board) was not adequately implementing its approved program to regulate surface coal mining and reclamation operations (KS–247). The Board is a duly constituted agency under the direction of the Kansas State Corporation Commission (KSCC) which is designated to administer the regulatory program. The Chairman of the KSCC also serves as the Chairman of the Board. The Board represents multiple interests, and its members include heads of State agencies, employees and operators of surface coal mines, and representatives from the general public. The Board's staff, headed by an Executive Director, implements the State program.

The Director, OSM, cited problems in Kansas' program implementation in several areas including (1) permitting, (2) inspection and enforcement, (3) administrative procedures and records, (4) civil penalty assessment, (5) bond release and (6) staffing. A more detailed account of the Director's concerns can be found in the May 31, 1983 Federal Register (48 FR 24073).

On April 14, 1983, the Governor responded to the Director's March 11, 1983 letter by providing assurances that Kansas would correct the deficiencies outlined in the Director's letter (KS–250). On May 8, 1983, the State requested an informal conference with OSM under the provisions of 30 CFR 733.12(c) (KS–250). The Director agreed to Kansas' request, notified the public (48 FR 24073) and held an informal conference with Board officials and the KCC on June 16, 1983, in Pittsburg, Kansas. (See KS–254 for conference transcript.)

At the informal conference, OSM requested that Kansas provide additional information on many of OSM's concerns. Kansas submitted additional written information on July 30, 1983 (KS–255), August 30, 1983 (KS–257), and September 30, 1983 (KS–259).

In August 1983, OSM's Annual Report on Kansas' Permanent Program was completed and submitted to Congress. The report contained an evaluation of the performance of the Kansas Mined Land Conservation and Reclamation Board in implementing its approved program for the period from April 1, 1982 to April 30, 1983 (KS–290).

A meeting was held between OSM and the State on November 10, 1983, to discuss OSM's concerns and the State's progress in resolving issues identified in the annual evaluation report (KS–260).

On November 17, 1983, after evaluating Kansas' performance for the