Red Bluff, CA [Revised]

That airspace extending upward from 700 feet above the surface within 2 miles each side of the Red Bluff VORTAC 347° radial extending from the VORTAC to 11.5 miles N of the VORTAC, and that airspace extending upward from 1,200 feet above the surface within a 20-mile radius of the Red Bluff VORTAC; within 9 miles each side of the Red Bluff VORTAC 291° radial, extending from the 20-mile radius area to 52 miles W of the VORTAC; within an arc of a 30-mile radius circle centered on Red Bluff VORTAC, extending from the N edge of V-195 to the W edge of V-23; within 9 miles W and 10 miles E of the Red Bluff VORTAC 342° radial, extending from the 20-mile radius area to 67 miles N of the VORTAC; within 10 miles W and 6 miles E of the Red Bluff VORTAC 015° radial, extending from the 20-mile radius area to 58 miles N of the Red Bluff VORTAC; within an area bounded by a line beginning at lat. 40°21'27" N, long. 121°54'40" W; to lat. 40°34'40" N, long. 121°52'30" W; to lat. 40°21'46" N, long. 121°56'45" W; to lat. 40°22'35" N, long. 122°01'00" W, to the point of beginning; and that airspace NE and E of Red Bluff in a 24-mile radius circle centered on the Red Bluff VORTAC, extending from the Red Bluff VORTAC 015° radial clockwise via the 24-mile arc to lat. 40°00'00" N.

Redding, CA [New]

That airspace extending upward from 700 feet above the surface within a 5-mile radius of Redding Municipal Airport (lat. 40°30'33" N, long. 122°17'32" W) within 2 miles W and 4 miles E of the Redding VOR 192° radial, extending from the 5-mile radius area to 10 miles S of the VOR, within 2 miles each side of the Redding ILS localizer N course, extending from the 5-mile radius area to 6 miles N of the threshold of Runway 18, excluding the portions within a 1-mile radius of Redding Sky Ranch Airport (lat. 40°29'55" N, long. 122°23'25" W) and Enterprise Sky Park (lat. 40°34'40" N, long. 122°19'15" W), and that airspace extending upward from 1,200 feet above the surface north of Redding within a arc of a 23-mile radius circle centered on Redding VOR, extending from the E edge of V-23 the W edge of V-25.

Issued in Los Angeles, California, on February 28, 1987.

Merle D. Clay,
Acting Manager, Air Traffic Division, Western-Pacific Region.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Placement of Para-fluorofentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice of proposed rulemaking is issued by the Administrator of the Drug Enforcement Administration (DEA) to place the narcotic substance para-fluorofentanyl into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801, et seq.). This proposed action by the DEA Administrator is based on data gathered and reviewed by DEA. If finalized, this proposed action would impose the regulatory controls and criminal sanctions of Schedule I on the manufacture, distribution and possession of para-fluorofentanyl.

DATE: Comments must be submitted on or before May 11, 1987.

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

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, 1405 I Street NW., Washington, DC 20537, Telephone: (202) 633-1306.

SUPPLEMENTARY INFORMATION: On February 7, 1986, the Administrator of the Drug Enforcement Administration issued a final rule in the Federal Register (51 FR 4722) temporarily placing N-(4-fluorophenyl)-N-[2-(2-phenylethyl)-4-piperidyl]propanamide, commonly referred to as para-fluorofentanyl, into Schedule I of the Controlled Substances Act (CSA). The final rule which became effective on March 10, 1986 was based on a finding that the emergency scheduling of para-fluorofentanyl 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 the year from the effective date of the order. However, if proceedings to schedule a substance pursuant to 21 U.S.C. 811(a)(1) have been initiated and are pending, the temporary scheduling of a substance may be extended for up to six months. Under this provision, the temporary scheduling of para-fluorofentanyl which would expire on March 10, 1987, may be extended to September 10, 1987. The DEA Administrator is ordering such an extension in a separate action.

DEA has gathered and reviewed the available information regarding the actual abuse and relative potential for abuse of para-fluorofentanyl. DEA, in conjunction with the National Institute on Drug Abuse (NIDA), has provided for the synthesis and biological testing of para-fluorofentanyl which has been completed. By letter dated October 27, 1986, the DEA Administrator submitted the data which DEA has gathered regarding para-fluorofentanyl and six other fentanyl analogs to the Assistant Secretary for Health, Department of Health and Human Services. In accordance with 21 U.S.C. 811(b), the DEA Administrator also requested a scientific and medical evaluation of the relevant information and a scheduling recommendation for para-fluorofentanyl from the Assistant Secretary for Health.

The following is a brief summary of the available information submitted to the Assistant Secretary for Health regarding para-fluorofentanyl.

Chemically, para-fluorofentanyl is N-(4-fluorophenyl)-N-[2-(2-phenylethyl)-4-piperidyl]propanamide. It behaves as a typical morphine-like substance in several pharmacological tests in mice and rats. Para-fluorofentanyl has a 90-minute duration of analgesic action and it is estimated to be about 100 times as potent and analgesic as morphine. Para-fluorofentanyl also substitutes completely for morphine in morphine-dependent withdrawn monkeys.

DEA laboratories have identified para-fluorofentanyl in drug evidence submissions from both the East Coast and West Coast of the United States. It was first identified in a two-ounce evidence submission from Los Angeles, California in 1981. In the fall of 1985, DEA laboratories identified substantial quantities of para-fluorofentanyl in exhibits associated with a clandestine laboratory producing para-fluorofentanyl and 3-methylfentanyl in Delaware.

Fentanyl analogs have been associated with more than 100 overdose deaths since 1980. These deaths were typical narcotic overdose and the cause of death in most cases was reported as pulmonary congestion due to intravenous "fentanyl" toxicity. The pharmacological profiles of para-fluorofentanyl and other fentanyl analogs are consistent with the production of narcotic overdose deaths.

There are no commercial manufacturers or suppliers of para-fluorofentanyl nor is it used therapeutically. The Assistant Secretary for Health, when notified of DEA's intention to emergency schedule para-fluorofentanyl, did not object to this action. The Assistant Secretary's concurrence meant that no Investigational New Drug exemptions (IND's) or approved New Drug Applications (NDA's) were in effect for para-fluorofentanyl. Neither the
Assistant Secretary for Health nor the Food and Drug Administration has notified DEA of any change in the marketing status of para-fluorofentanyl. If a substance cannot lawfully be marketed under the Food, Drug and Cosmetic Act, that substance, under the GSA, has no currently accepted medical use in treatment in the United States and is not accepted as safe for use under medical supervision.

The DEA Administrator, based on the information gathered and reviewed by his staff and after consideration of the factors in 21 U.S.C. 811(c), believes that sufficient data exists to propose that para-fluorofentanyl be placed into Schedule I of the CSA pursuant to 21 U.S.C. 811(a). The specific findings required pursuant to 21 U.S.C. 811 and 812 for a substance to be placed into Schedule I are as follows:

1. The drug or other substance has a high potential for abuse.
2. The drug or other substance has no currently accepted medical use in treatment in the United States.
3. There is a lack of accepted safety for the drug or other substance under medical supervision.

The DEA Administrator contends that there is adequate data to support each of the findings for placement of para-fluorofentanyl into Schedule I of the CSA. The DEA Administrator further contends that adequate data exists to classify para-fluorofentanyl as an opiate as defined in 21 U.S.C. 802(16) and hence as a narcotic as defined in 21 U.S.C. 802(17).

Before issuing a final rule in this matter, the DEA Administrator will take into consideration the scientific and medical data, the findings and scheduling recommendation of the Secretary of the Department of Health and Human Services in accordance with 21 U.S.C. 811(b). The Administrator will also consider relevant comments from other concerned parties.

Interested persons are invited to submit their comments, objections or requests for hearing in writing with regard to this proposal. Requests for a hearing should state with particularity the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the Administrator, Drug Enforcement Administration, 1405 I Street NW., Washington, DC 20537. Attention: DEA Federal Register Representative.

In the event that comments, objections or requests for a hearing raise one or more issues which the Administrator finds warrant a hearing, the Administrator shall order a public hearing by notice in the Federal Register, summarizing the issues to be heard and setting the time for the hearing.

Pursuant to Title 5, United States Code, section 805(b), the Administrator certifies that the proposed placement of para-fluorofentanyl into Schedule I of the CSA 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 substance proposed for control in this notice has not legitimate use or manufacture in the United States. In accordance with the provisions of Title 21, United States Code, section 811(a), this proposal to place para-fluorofentanyl into Schedule I is a formal rulemaking "on the record after opportunity for a hearing."

Such 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 (40 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 Departments of Justice regulations (28 CFR 0.100), the Administrator hereby proposes that 21 CFR 1308 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 adding a new paragraph (b)(37) and redesignating existing paragraphs (b)(37) through (b)(48) as (b)(36) through (b)(49) as follows:

§ 1308.11 Schedule I.

(b) (37) para-fluorofentanyl [(N-(4-fluorophenyl)-N-[1-(2-phenoxyethyl)-1-piperidyl]propanamido) hydrochloride]

3. Section 1308.11 is further amended by removing paragraph (g)(9).

Dated: March 6, 1987.

John C. Lawn,
Administrator, Drug Enforcement Administration.

[FR Doc. 87-5090 Filed 3-9-87; 8:45 am]

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