DEPARTMENT OF JUSTICE
Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Temporary Placement of 3-Methylfentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration (DEA) is issuing this notice to temporarily place 3-methylfentanyl into Schedule I of the Controlled Substances Act (CSA) pursuant to the emergency scheduling provisions of the CSA. This action is based on a finding that the scheduling of 3-methylfentanyl 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 3-methylfentanyl.

EFFECTIVE DATE: On April 25, 1985, 3-methylfentanyl will be subject to Schedule I control.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washinton, D.C. 20537, Telephone: (202) 633-1386.

SUPPLEMENTARY INFORMATION: The Comprehensive Crime Control Act of 1984 (Pub. L. 98-473) amended section 201 of the 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. Scheduling a substance under this emergency provision may be done without regard to the requirements of section 201(b) of the CSA (21 U.S.C. 811(b)) relating to the Secretary of Health and Human Services. 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)).

As required by section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)), the Acting Administrator has notified the Secretary of Health and Human Services of his intention to place this substance in Schedule I pursuant to the emergency scheduling provisions. Such action may not take effect until the expiration of thirty days after notification is transmitted to the Secretary.

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 (4) the history and current pattern of abuse, (5) the scope, duration and significance of abuse, and (6) 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 or variations of existing controlled substances, or other new substances, which have a psychedelic, stimulant or depressant effect and have a high potential for abuse. The fentanyl analogs, including 3-methylfentanyl, are examples of such designer drugs which Congress clearly intended to be subject to the emergency scheduling authority as imminent hazards to the public safety."

Information available to DEA indicates that a series of analogs of the Schedule II narcotic analgesic, fentanyl, have been clandestinely produced, distributed and abused on the West Coast since late 1979. The first of these analogs detected was alpha-methylfentanyl, sold on the street as "China White" or "synthetic heroin." Using the traditional scheduling process pursuant to section 201(b) and (c) of the CSA (21 U.S.C. 811(b) and (c)), DEA placed alpha-methylfentanyl into Schedule I of the CSA on 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. Available information did not indicate that these analogs were causing a serious public safety hazard until 1984. Increased reports of the distribution, abuse and health hazards of the fentanyl analogs coincided with the identification of 3-methylfentanyl by DEA laboratories in submissions from the San Francisco Bay area in late 1983 and 1984.

N-[3-methyl-1-[2-phenylethyl]-4-piperidyl]-N-phenylpropanamide, or 3-methylfentanyl is an extremely potent morphine-like analgesic substance with a rapid onset and short duration of action. 3-methylfentanyl exhibits a pharmacological profile similar to that of fentanyl, morphine and heroin. In tests which determine morphine-like analgesic effects on rats, some forms of 3-methylfentanyl effectively produced analgesia at doses as low as 0.00058 mg/
kg, compared to 3.15 mg/kg for morphine, thus making 3-methylfentanyl effective at 1/5000th the dose of morphine. The acute toxicity, measured as the LD$_{50}$ in rats of 3-methylfentanyl (1.08 mg/kg) is over 200 times lower than that for morphine (238 mg/kg). DEA is unaware of any legitimate medical use or manufacturers of 3-methylfentanyl in the United States.

3-methylfentanyl was first identified by a DEA laboratory in drug samples submitted from Fresno, California in December, 1983. During 1984, forensic laboratories identified 3-methylfentanyl in 33 drug samples; 25 of them since August, 1984. An additional 5 samples containing 3-methylfentanyl were analyzed by DEA laboratories in February, 1985. One of these recent samples was part of a 455g (approximately 1 pound) exhibit obtained in Santa Clara County, California. All but one of the 40 samples of 3-methylfentanyl analyzed by forensic laboratories originated in the San Francisco Bay area; the lone exception was an exhibit obtained in Brooklyn, New York in July, 1984 and containing a fentanyl analog, most probably 3-methylfentanyl.

Narcotic treatment program directors in California report an increasing number of fentanyl users seeking treatment in 1984. Although the specific fentanyl analogs were not identified in the urine samples of applicants, it is most likely that 3-methylfentanyl is the responsible analog. All of the reports of fentanyl analog use by individuals seeking treatment since July, 1984 were from the San Francisco Bay area.

At least 3 overdose deaths associated with fentanyl analogs were reported in 1984; 26 of these since August 1, 1984. Twenty of the overdose deaths occurred in the San Francisco Bay area where 3-methylfentanyl has been specifically identified in powder samples. Deaths were caused by pulmonary congestion due to intravenous "fentanyl" toxicity. Concentrations of the fentanyl-like substance in the body fluids of the overdose victims, in many cases, were extremely low (less than 1 ng/ml) which is consistent with the use of an extremely potent substance such as 3-methylfentanyl.

Impurities, precursors and by-products found in the samples of 3-methylfentanyl indicate that it is produced in clandestine laboratories using a procedure not described in the chemical literature. The suspected process results in the formation of unwanted by-products. Clandestinely produced substances pose additional health and safety risks because the purity and concentration of active ingredients is unknown and inconsistent.

The pattern of abuse of fentanyl analogs in general and 3-methylfentanyl in particular parallels that of heroin. Fentanyl analogs, including 3-methylfentanyl, are sold on the street as "China White", "synthetic heroin," "heroin" or "fentanyl." The packaging is identical to that of heroin: It is "cut" with lactose and mannitol and recently mixed with cocaine. 3-methylfentanyl is abused by known heroin addicts and used intravenously after it is dissolved in heated water.

The exact magnitude of the production, distribution and use of 3-methylfentanyl is difficult to determine due to the minute quantities of material present in powder samples (micrograms) and biological samples (submicrograms) and the difficulty in detecting these quantities by laboratory analyses. In light of the above, there is little doubt that the prevalence of 3-methylfentanyl is underreported. The number of 3-methylfentanyl samples analyzed by forensic laboratories, the number of 3-methylfentanyl associated overdose deaths and the number of narcotic treatment program admissions due to fentanyl analog use during the latter half of 1984 is thus highly significant.

The data described above clearly shows that the production, distribution and abuse of 3-methylfentanyl currently pose a very serious hazard to the public safety, at least in California. Although there has been minimal information concerning the use of fentanyl analogs, including 3-methylfentanyl, outside of California (2 overdose deaths in Oregon associated with a fentanyl-like substance and 1 powder sample in Brooklyn, New York which is probably 3-methylfentanyl), there is a very high potential for the spread of 3-methylfentanyl to other areas of the country.

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, the Acting Administrator has considered the following factors described in section 201(c) of the CSA (21 U.S.C. 811(c)) relative to making a determination of whether 3-methylfentanyl poses an imminent hazard to the public safety:

(4) Its history and current pattern of abuse.

(5) The scope, duration and significance of abuse.

(6) What, if any, risk there is to the public health.

Based on a consideration of these factors and other relevant information, the Acting Administrator, pursuant to section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, finds that:

(1) 3-methylfentanyl poses an imminent hazard to the public safety.

(2) Scheduling 3-methylfentanyl in Schedule I of the CSA, at least on a temporary basis, is necessary to avoid an imminent hazard to the public safety.

The Acting Administrator has transmitted notice of his intention to temporarily place 3-methylfentanyl into Schedule I to the Secretary of Health and Human Services. Comments submitted by the Secretary in response to the notification, including whether there is an exemption or approval in effect for 3-methylfentanyl under the Federal Food, Drug and Cosmetic Act, shall be taken into consideration by the Acting 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 Acting Administrator hereby orders that on April 25, 1985, 3-methylfentanyl [N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropionamide], its optical and geometric isomers, salts and salts of isomers, be placed into Schedule I of the CSA (21 U.S.C. 801 et seq.) unless the Acting Administrator gives notice in the Federal Register that this order is rescinded prior to April 25, 1985.

The temporary placement of 3-methylfentanyl in Schedule I under 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 3-methylfentanyl 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 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 Acting Administrator affords the opportunity for comments to be submitted concerning this matter. Comments should be submitted in...
DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 178

Commerce in Firearms and Ammunition; Format for Firearms Acquisition and Disposition Record

CFR Correction

The Office of the Federal Register is correcting a typesetting error in the Firearms Acquisition and Disposition Record format appearing in 27 CFR Part 178.125.

The correct format was originally published at 33 FR 15555, Dec. 14, 1968, as 26 CFR 178.125, and was incorporated correctly into the subsequent editions of Title 26 CFR from 1969 through 1974. In 1975, the regulations in Title 26, Subchapter E (Parts 170–299) were transferred to and redesignated as Title 27, Subchapter M, (Parts 170–299) by a document published at 40 FR 16835, April 15, 1975. The correct format for 27 CFR 178.125 appeared in all subsequent editions of Title 27 CFR through the edition of April 1, 1980. The typesetting error first occurred in the April 1, 1981 edition of Title 27, CFR Parts 1 to 199, and the error has been repeated in the later editions of the same volume issued as of April 1 in 1982, 1983 and 1984. The BATF brought the error to the attention of the Office of the Federal Register, subsequent to release of the 1984 CFR edition.

An official of the BATF has informed the OFR by letter that "some licensees have used the incorrect format of the firearms record in 27 CFR 178.125 as a guide, and have made a supply of these forms for their future use. Licensees may continue to use the forms with the incorrect format until their supplies are exhausted. However, all of the information required by 27 CFR Part 178.125 must still be included on either format used."

The correct format should read as set forth below.

§ 178.125 Record of receipt and disposition.

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