Veterinary Medicine (21 CFR 5.83), Part 558 is amended as follows:

1. In § 558.355 by adding new paragraphs (b)(5) and (f)(1)(xiii) to read as follows:

§ 558.355 Monensin.

* * * * *

(b) * * *

(5) To 000007: 45 grams per pound as monensin sodium as provided by No. 000986 in § 510.600(c) of this chapter, paragraph (f)(1)(xiii).

* * * * *

(f) * * *

(1) * * *

(xiii) *Amount per ton.* Monensin, 90 to 110 grams, plus 5 grams virginiamycin.

(*a*) *Indications for use.* As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima,* and *E. mivati;* for increased rate of weight gain and improved feed efficiency.

(*b*) *Limitations.* For broiler or fryer chickens; do not feed to laying chickens; feed continously as sole ration; withdraw 5 days before slaughter; as monensin sodium provided by No. 000986 in § 510.600 of this chapter; virginiamycin provided by No. 000007 in § 510.600 of this chapter.

2. In § 558.635 by adding new paragraph (f)(3) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(f) * * *

(3) Virginiamycin may be used in accordance with the provisions of this section in the combinations provided, as follows:

(i) Monensin sodium in accordance with § 558.355.

(ii) [Reserved]

Effective date. This amendment is effective September 22, 1981.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: September 15, 1981.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 81-27485 Filed 9-21-81; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of Alpha-Methylfentanyl in Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Acting Administrator of the Drug Enforcement Administration to place the substance, alpha-methylfentanyl, into Schedule I of the Controlled Substances Act (CSA). As a result of this rule, the possession, distribution, manufacture, importation and exportation of alpha-methylfentanyl is subject to the control mechanisms and criminal sanctions of Schedule I.

EFFECTIVE DATE: September 22, 1981.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: A notice was published in the Federal Register on Wednesday, August 5, 1981 (46 FR 39848-9), proposing that alpha-methylfentanyl be placed into Schedule I of the Controlled Substances Act (21 U.S.C. 801 *et seq.*). This notice further stated that the Acting Administrator found that the abuse of alpha-methylfentanyl has had a substantial and detrimental effect on the public health and safety. Consequently, the Acting Administrator gave notice that the effective data of control of alpha-methylfentanyl would be the date of publication of the final order placing it into Schedule I unless evidence showing why this should not be was presented. All interested parties were given until September 4, 1981 to submit their comments or objections in writing regarding this proposal.

Several comments concerning the proposed placement of alpha-methylfentanyl into Schedule I were submitted by Ohio Medical Products. Their comments refer to the compound 3-methylfentanyl or 1-(2-phenylethyl)-3-methyl-4-(N-propanoyl-anilino) piperidine which was not proposed for control and not alpha-methylfentanyl as proposed in the August 5, 1981 notice (46 FR 39848-9). However, a number of the comments are applicable to either compound and therefore will be addressed in this final order.

Ohio Medical Products suggests the use of another nomenclature system to describe the chemical structure of alpha-methylfentanyl. In addition to that used in the proposal, the name 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine will be included in the listing to describe alphamethylfentanyl. The question of which isomers are to be covered by the proposed regulation was raised by Ohio Medical Products. Alpha-methylfentanyl was proposed for control in Schedule I (21 CFR 1308.11(b)) which includes the listed opiates and their isomers with the term isomers defined in 21 CFR 1308.02 as the optical isomer. Ohio Medical Products further questions why alpha-methylfentanyl was singled out for Schedule I control from the many fentanyl derivatives which they suggest are likely to have high abuse potential. As described in the Federal Register proposal to place alpha-methylfentanyl in Schedule I, this substance has been identified in illicit drug traffic, reported by Narcotic Treatment Program Directors as abused by heroin addicts and associated with numerous drug overdose deaths. Specific studies conducted under National Institute on Drug Abuse contracts have shown alpha-methylfentanyl to be morphine-like and capable of producing physical dependence. Although other fentanyl derivatives may have pharmacological properties which are commensurate with a potential for abuse, they have not been specifically studied to determine whether they have an abuse potential nor is there any evidence that the other derivatives are being abused.

Ohio Medical Products recommends that alpha-methylfentanyl be placed into Schedule II of the CSA until research has shown that it has no potential for clinical use. 21 U.S.C. 812(b)(2) lists the criteria for placing a substance into Schedule II and they are as follows:

(A) The drug or other substance has a high potential for abuse;

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions; and

(C) Abuse of the drug or other substance may lead to severe psychological or physical dependence.

Alpha-methylfentanyl satisfies criteria (A) and (C) but it has no accepted medical use in treatment in the United States. The criteria for Schedule I are:

(A) The drug or other substance has a high potential for abuse;

(B) The drug or other substance has no currently accepted medical use in treatment in the United States; and

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Using the criteria for inclusion of a substance in any of the five schedules of the CSA, as outlined in 21 U.S.C. 812(b), alpha-methylfentanyl best fits the criteria for Schedule I control. Should there be an approved medical use for alpha-methylfentanyl in the future as determined by the Food and Drug Administration, administrative mechanisms exist for the transfer of this substance to the appropriate schedule.

Ohio Medical Products maintains that placing alpha-methylfentanyl into Schedule I will create an unnecessary regulatory burden on researchers. The main regulatory requirement imposed on a researcher using a Schedule I substance is that he or she is registered with DEA for handling that particular substance. The requirements attendant to a Schedule I research registration are not particularly onerous when one considers the serious health consequences associated with the abuse of alpha-methylfentanyl. Further, it is highly probable that a researcher who would want to work with alpha-methylfentanyl would be registered with DEA for other substances used for comparison. An amended registration to include alpha-methylfentanyl imposes only a minimal regulatory burden on these individuals.

A letter was received from Mr. Ronald D. Veteto who objects to the control of alpha-methylfentanyl and drugs in general. This comment questions the general philosophy of drug control but provides no valid reason, given the requirements of the Controlled Substances Act, for not placing alpha-methylfentanyl under control.

No other comments or objections were received, nor were there any requests for a hearing. Based upon the investigations and review conducted by the Drug Enforcement administration and upon the scientific and medical evaluation and recommendation of the Assistant Secretary for Health, Department of Health and Human Services, received in accordance with 21 U.S.C. 811(b), the Acting Administrator of the Drug Enforcement Administration, pursuant to 21 U.S.C 811(a) and 811(b), finds that:

(1) Based on information now available, alpha-methylfentanyl has a high potential for abuse;

(2) Alpha-methylfentanyl has no currently accepted medical use in treatment in the United States; and

(3) Alpha-methylfentanyl lacks accepted safety for use under medical supervision.

The above findings are consistent with the placement of alpha-methylfentanyl into Schedule I of the Controlled Substances Act. The Acting Administrator further finds that alpha-methylfentanyl is an opiate as defined in 21 U.S.C. 802(17) since it has addiction-forming and addition-sustaining liabilities similar to those of morphine. Consequently, alpha-methylfentanyl is a narcotic since the definition of narcotic, as stated in 21 U.S.C. 802(16) (A) includes: "* * * opium, coca leaves and opiates."

Neither of the comments received gave any reason for not making the control of alpha-methylfentanyl in Schedule I effective when this final order is published. All regulations applicable to Schedule I narcotic substances are effective on (date of publication) with respect to alpha-methylfentanyl. However, individuals registered with the Drug Enforcement Administration in accordance with Parts 1301 or 1311 of Title 21 of the Code of Federal Regulations and who currently possess alpha-methylfentanyl may continue to do so pending submission of an amended registration application no later then October 22, 1981.

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports alpha-methylfentanyl, 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.

2. *Security.* Alpha-methylfentanyl 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 alpha-methylfentanyl 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 alpha-methylfentanyl 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 alpha-methylfentanyl 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 maintain such records on alpha-methylfentanyl.

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 alpha-methylfentanyl.

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

10. *Criminal Liability.* The Acting Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to alpha-methylfentanyl 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 Acting Administrator certifies that the placement of alpha-methylfentanyl 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 initial control of a substance 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 12991 (46 FR 13193).

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Under the authority vested in the Attorney General by section 201(a) of the Act (21 U.S.C. 811(a)) and delegated to the Acting Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR Part 0.100), the Acting Administrator hereby orders that:

1. 21 CFR 1308.11(b)(6)–(45) is redesignated as 21 CFR 1308.11(b)(7)–(46); and

2. A new § 1308.11(b)(6) is added to read as follows: § 1308.11 Schedule I.

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(6) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine)	9814

* * * * *

Dated: September 16, 1981.

Francis M. Mullen, Jr.,

Acting Administrator, Drug Enforcement Administration.

[FR Doc. 81-27553 Filed 9-21-81; 8:45 am]

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