of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 558 are amended as follows:

PART 520— ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.445b [Amended]

2. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraph (d)(4)(iii)(C) by removing ''012286, 053389, and 054273'' and adding in its place ''000010, 012286, and 053389''.

§ 520.2345d [Amended]

3. Section 520.2345d *Tetracycline hydrochloride soluble powder* is amended in paragraph (a)(1) by removing ''054273,'' and adding ''000010,'' before ''046573''.

PART 558— NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

4. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.15 [Amended]

5. Section 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* is amended in paragraphs (g)(1) and (g)(2) by removing ''Fermenta Animal Health Co.'' and adding in its place ''Boehringer Ingelheim Vetmedica, Inc.''

Dated: June 28, 1999.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–17761 Filed 7–12–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[DEA–183F]

21 CFR Part 1308

Schedules of Controlled Substances: Placement of Ketamine into Schedule III

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance ketamine, including its salts, isomers, and salts of isomers, into schedule III of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). As a result of this rule, the regulatory controls and criminal sanctions of schedule III will be applicable to the manufacture, distribution, dispensing, importation and exportation of ketamine and products containing ketamine.

EFFECTIVE DATE: August 12, 1999.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

Ketamine hydrochloride is marketed in the United States as a general anesthetic for use in human medicine under the trade name Ketalar®. It is also marketed as a veterinary product under various names including Ketajet®, Ketaset®, and Vetalar®. Since 1992, more than 775 reports of ketamine diversion or abuse have been received by the DEA. More than 568 law enforcement reports described encounters of individuals who sold the drug, who had it in their possession and/or were under its influence. Veterinary clinic burglaries which were directed at ketamine were described also. The balance of the reports were of ketamine abuse related hospital emergency department visits.

The wide geographic distribution and prevalence of diversion and/or abuse of ketamine, the spreading notoriety of ketamine as a party drug, Special 'K' or 'K', and the involvement of teenagers and young adults caused the DEA to submit to the Department of Health and Human Services (DHHS) information related to each of the eight factors which are determinative of control under the CSA. The DHHS responded by letter, recommending that ketamine be added to schedule III.

The pharmacological and behavioral effects of ketamine are similar, but somewhat less intense and shorter in duration, to those of the schedule II substance, phencyclidine (PCP). Low dose intoxication with ketamine results in impaired attention, learning, and memory functions. Higher doses may result in ataxia, dizziness, elevated blood pressure, mental confusion, hyperexcitability, catalepsy (the inability to move), amnesia, convulsions, a delusional dream-like state, hallucinations, and psychosis. Long-term use of ketamine is associated with hallucinatory flashbacks, an inability to concentrate, psychological dependence, and tolerance. Reports of ketamine abuse leading to physical or psychological dependence consistent with schedule III criteria have been published.

Diversion of ketamine pharmaceutical products from practitioners has been the most frequently documented source of the drug, with the primary sources being veterinary clinics. The liquid pharmaceutical product is injected or, more commonly, evaporated and the resultant power inhaled (snorted). Clandestine manufacture of ketamine has not been encountered. In contrast to that of PCP, the synthesis of ketamine is difficult.

Notice of Proposed Rule Making

Relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health in accordance with section 201(b) of the CSA [21 U.S.C. 811(b)], and the independent review of the DEA, the Deputy Administrator of the DEA, pursuant to Sections 201(a) and 201(b) of the CSA [21 U.S.C. 811(a) and 811(b) proposed the placement of ketamine, including its salts, isomers, and salts of isomers, into schedule III of the CSA in an April 9, 1999, **Federal Register** notice (64 FR 17299). The notice provided an opportunity for all interested persons to submit their comments or objections in writing on the proposed scheduling of ketamine on or before June 8, 1999.

Comments

The DEA received five comments regarding the proposal. Comments in support of the proposal were received from the American Animal Hospital Association (AAHA), the American Veterinary Medical Association (AVMA), the American Association of Equine Practitioners (AAEP) and a practicing veterinarian. The AAHA, which represents 16,000 veterinary care providers, commented that the movement of ketamine into Schedule III was in the best interest of the veterinary industry and the general public. The AVMA, on behalf of 62,000 members, stated that the security and record keeping required of Schedule III controlled substances will prevent diversion and unauthorized use of ketamine while providing a reasonable mechanism for the continued, responsible use of ketamine for legitimate purposes by members of the veterinary profession. The AAEP which reaches 3.2 million horse owners through its more than 6,200 members world wide strongly supports the placement of ketamine into Schedule III.

The group commented that anesthesia in the horse poses unique dangers to both handlers and the horse; that ketamine has proven to be the safest induction agent known and remains an important medication to the equine practitioner; that the equine veterinary community is keenly aware of the public health concerns associated with this drug; and that many veterinary practices have already taken precautionary steps to prevent its misuse by keeping the drug restricted and secured. A veterinarian whose hospital in Pennsylvania was broken into by individuals seeking ketamine strongly supports the placement of ketamine into Schedule III and notes that publicity of the mandatory security measures will discourage potential burglars.

The Phoenix Scientific, Inc., a supplier of generic veterinary ketamine hydrochloride injection products, opposed the proposal. In summary, the company posited that: 1. The Fort Dodge Animal Health advocacy of the placement of ketamine into Schedule III might be an attempt to limit the production and distribution of the generic equivalent by reputable firms; 2. the problem of diversion of ketamine is not a factor which needs to be addressed further at the manufacturers' level; 3. compliance with the DEA requirements will cause substantial price increases and not stop diversion; and 4. the manufacturer(s) will be burdened with assisting law enforcement and forensic labs throughout the country because a field test for the identification of ketamine does not exist. Further, the company asked that ''a reasonable amount of time'' be allowed for coming into compliance with the regulatory requirements if the proposed action were finalized.

In response, the Deputy Administrator finds that the comments do not relate to the factors determinative of control of a substance [21 U.S.C. 811(c)] or the criteria for placement of a substance in a particular schedule [21 U.S.C. 812(b)]. Therefore, he need not address the objections. In relation to the commenter's request for the allowance of sufficient time for coming into compliance with the Schedule III regulatory requirements, the Deputy Administrator notes that, as described below, the DEA will entertain any justified request for an extension of time in the event that the regulations impose special hardships.

Findings

The Deputy Administrator of the DEA, taking into consideration the comments which were received in response to the publication of the proposed rule, and based on the investigations and review conducted by his staff and relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health, received in accordance with Section 201(b) of the Act [21 U.S.C. 811(b)], finds, pursuant to Sections 201(a) and 201(b) of the Act [21 U.S.C. 811(a) and 811(b)], that:

(1) Ketamine has a potential for abuse less than the drugs or other substances in Schedules I and II;

(2) Ketamine has currently accepted medical use in treatment in the United States; and

(3) Abuse of ketamine may lead to moderate or low physical dependence or high psychological dependence.

Scheduling Action

Based on these findings, the Deputy Administrator of the DEA concludes that ketamine, including its salts and isomers, and salts of isomers, warrants control in Schedule III in the CSA. The Schedule III controls of ketamine will become effective on August 12, 1999. In the event that the regulations impose special hardships on any registrant, the DEA will entertain any justified request for an extension of time to comply with the Schedule III regulations regarding ketamine. The applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports ketamine or who engages in research or conducts instructional activities or chemical analysis with respect to this substance, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations on and after August 12, 1999. Any person who is currently lawfully engaged in any of the above activities must submit an application for registration by August 12, 1999. Any such person may then continue their lawful activities until the DEA has approved or denied that application.

2. *Disposal of stocks.* Any person who elects not to obtain a Schedule III registration or is not entitled to such registration must surrender all quantities of currently held ketamine in accordance with procedures outlined in 21 CFR 1307.21 on or before August 12, 1999, or may transfer all quantities of currently held ketamine to a person registered under the CSA and authorized to possess Schedule III control substances on or before August 12, 1999. Ketamine to be surrendered to DEA must be listed on a DEA Form 41, ''Inventory of Controlled Substances Surrendered for Destruction.'' DEA Form 41 and instructions can be obtained from the nearest DEA office.

3. *Security.* Ketamine must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

4. *Labeling and packaging.* All commercial containers of ketamine, which are packaged on or after January 13, 2000, must have the appropriate Schedule III labeling as required by §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations. Commercial containers of ketamine packaged before January 13, 2000 and not meeting the requirements specified in §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations may be distributed until May 15, 2000. On and after May 15, 2000 all commercial containers of ketamine must bear the CIII labels as specified in §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Registrants possessing ketamine are required to take inventories pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations.

6. *Records.* All registrants must keep records pursuant to §§ 1304.03, 1304.04 and 1304.21–1304.23 of Title 21 of the Code of Federal Regulations.

7. *Prescriptions.* All prescriptions for ketamine are to be issued pursuant to §§ 1306.03–1306.06 and 1306.21–1306.26 of Title 21 of the Code of Federal Regulations. All prescriptions for products containing ketamine issued on or before September 13, 1999, if authorized for refilling, shall as of that date be limited to five refills and shall not be refilled after January 13, 2000.

8. *Importation and Exportation.* All importation and exportation of ketamine shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

9. *Criminal Liability.* Any activity with ketamine not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful on or after August 12, 1999.

In accordance with the provisions of the CSA [21 U.S.C. 811(a)], this action 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, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, Section 3(d)(1). The Deputy Administrator, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this rule and by

approving it, certifies that it will not have a significant economic impact on a substantial number of small business entities. Ketamine products are prescription drugs used as anesthetics in hospitals and clinics. Handlers of ketamine are likely to handle other controlled substances which are already subject to the regulatory requirements of the CSA.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule, as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the United States, on the relationship between the national government and the United States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 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) unless otherwise noted.

2. Section 1308.13 is amended by redesignating the existing paragraphs (c)(5) through (c)(11) as (c)(6) through (c)(12) and by adding a new paragraph (c)(5) to read as follows:

§ 1308.13 Schedule III.

* * * * *

(c) * * *

(5) Ketamine, its salts, isomers, and salts of isomers	7285
[Some other names for ketamine: (±)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone].	

* * * * *

Dated: July 7, 1999.

Donnie R. Marshall,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 99–17803 Filed 7–12–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1, 20, 25, 31, and 40

[TD 8828]

RIN 1545–AW41

Electronic Funds Transfers of Federal Deposits

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the deposit of Federal taxes by electronic funds transfer (EFT). The final regulations affect certain taxpayers required to make deposits of Federal taxes. For calendar years beginning after 1999, the final regulations provide rules under which certain taxpayers must make deposits by EFT.

DATES: *Effective Date:* These regulations are effective July 13, 1999.

Applicability Date: For dates of applicability, see § 31.6302–1(h)(2).

FOR FURTHER INFORMATION CONTACT: Vincent Surabian, (202) 622–4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1), the Estate Tax Regulations (26 CFR part 20), the Gift Tax Regulations (26 CFR part 25), the Employment Taxes and Collection of Income Tax at Source Regulations (26 CFR part 31), and the Excise Tax Procedural Regulations (26 CFR part 40). On March 23, 1999, a notice of proposed rulemaking was published in the **Federal Register** (64 FR 13940). A public hearing originally scheduled in the notice of proposed rulemaking for May 11, 1999, was canceled as there were no requests to speak. Three written comments were received. After consideration of all comments, the proposed regulations are adopted by this Treasury decision.

Explanation of Provisions

Section 6302(h) requires that, beginning in fiscal year 1999, 94 percent of employment taxes and 94 percent of other depository taxes be collected by EFT. The IRS and Treasury Department previously concluded that the deposit threshold had to be set at $50,000 to satisfy this statutory requirement. More recent experience suggests, however, that the statutory requirement can be satisfied even if the threshold is set at a substantially higher level. Moreover, an increase in the threshold would allow small businesses to make the transition to the EFT system at their own pace as they adopt electronic funds transfer in their other business operations. Accordingly, the final regulations increase the deposit threshold to $200,000 in aggregate Federal tax deposits during a calendar year.

The new $200,000 aggregate deposits threshold will be applied initially to 1998 deposits, and taxpayers that exceed the threshold in 1998 will be required to deposit by EFT beginning in 2000. Taxpayers that first exceed the threshold in 1999 or a subsequent year will similarly be required to deposit by EFT beginning in the second succeeding calendar year. A taxpayer that exceeds the threshold will not be permitted to resume making paper coupon deposits if its deposits fall below $200,000 in a subsequent year. Although a similar rule applies under the current regulations, taxpayers that are currently required to deposit by EFT will be given a fresh start and will not be required to use EFT unless they exceed the $200,000 threshold in 1998 or a subsequent calendar year.

The final regulations also expand the types of nondepository tax payments for which voluntary payment by EFT is allowed to include nondepository payments of Federal income, estate and gift, employment, and various specified excise taxes.

Public Comments

Two commentators on the proposed regulations opposed the increase in the threshold to $200,000. They were concerned that financial institutions