

**DEPARTMENT OF JUSTICE****Drug Enforcement Administration****21 CFR Part 1308****Schedules of Controlled Substances; Placement of Preparations Which Contain Both Tiletamine and Zolazepam Into Schedule III****AGENCY:** Drug Enforcement Administration, Justice.**ACTION:** Final rule.

**SUMMARY:** This final rule, issued by the Administrator of the Drug Enforcement Administration, places preparations which contain both tiletamine and zolazepam into Schedule III of the Controlled Substances Act. The effect of this action is to facilitate the marketing of a veterinary pharmaceutical product while minimizing the likelihood of the product being abused.

**EFFECTIVE DATE:** February 20, 1987.

**FOR FURTHER INFORMATION CONTACT:** Howard McClain, Jr., Chief, Drug Control Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 833-1366.

**SUPPLEMENTARY INFORMATION:** A proposed rule was published in the *Federal Register* on August 11, 1986 (51 FR 28727-28729), proposing that the substances, tiletamine and zolazepam, be placed into Schedule I and that preparations containing equal weights of both substances be placed into Schedule III of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). The proposed rule reinstated an action which was commenced in 1981 (46 FR 35529-35531, July 9, 1981). The 1981 action was initiated by the then Administrator of the Drug Enforcement Administration (DEA) in response to a recommendation from the then Acting Assistant Secretary for Health, Department of Health and Human Services (HHS), who, by letter of March 18, 1981, recommended that the substances, tiletamine and zolazepam, be placed into Schedule III of the CSA when the Food and Drug Administration (FDA) approved the New Animal Drug Application (NADA) for a tiletamine-zolazepam combination drug product. Tiletamine is a chemical analog of phencyclidine and has pharmacological properties similar to that Schedule II substance. Zolazepam is a chemical analog of the Schedule IV benzodiazepines and produces at least some of the same effects as those substances. The combination of tiletamine and zolazepam, in a 1-to-1

ratio, has been developed as an anesthetic agent for dogs and cats.

The then Administrator, based on the determination that individually the ingredients were not approved for marketing as therapeutic agents, found that neither tiletamine nor zolazepam met a finding required for inclusion in Schedule III [see 21 U.S.C. 812(b)(3)(B)] but did fulfill the criteria for Schedule I. In contrast, the tiletamine-zolazepam combination, upon approval of the NADA, would have a currently accepted medical use in the United States and would fulfill the criteria for inclusion in Schedule III. In a proposed rule, published in the *Federal Register* (46 FR 35529-35531, July 9, 1981), he proposed that tiletamine and zolazepam each be included in Schedule I and that, upon approval of the NADA, the pharmaceutical product be placed in Schedule III. Comments supporting the proposed action were received from the American Veterinary Medical Association. Objections to the placement of tiletamine and zolazepam into Schedule I were received from the American Association of Zoo Veterinarians and the Warner-Lambert Company. The latter, the sponsor of the NADA at that time, requested an administrative hearing.

On December 8, 1981, the then Administrator withdrew the proposed rule as it applied to the control of tiletamine and zolazepam in Schedule I and reaffirmed the proposed placement of preparations containing equal amounts of both substances into Schedule III (46 FR 60008-60009). The then Administrator denied the request for a hearing since withdrawal of the proposed action obviated its necessity and stated that the drug control action, as it applied to the mixture, would be finalized when the FDA approved the NADA for the combination product. No comments or objections were received in response to that announcement. On April 9, 1982, the then Acting Director of the FDA Bureau of Veterinary Medicine approved the NADA for the combination product (47 FR 15328-15329). The Warner-Lambert Company did not pursue the marketing of the product and a final rule was not issued.

In 1985, A.H. Robins Company, the current sponsor of the product (51 FR 24141-24142, July 2, 1986), notified DEA of its desire to market the product. In view of the time which had elapsed since the proposed rule was issued, the current Administrator initiated the drug control process anew and again proposed that tiletamine and zolazepam be placed into Schedule I and that preparations containing equal weights of

each substance be placed into Schedule III (51 FR 28727-28729, August 11, 1986).

Interested parties were given until September 10, 1986 to submit written comments or objections regarding this matter. One response was received. In his submission, Mr. Robert T. Angarola commented on the proposal, in particular, as it related to the control of zolazepam. He argued the relative importance of the individual findings required for each schedule and the treatment previously given 35 benzodiazepines. Mr. Angarola maintained that if zolazepam were included in the CSA it should be listed in Schedule IV, not in Schedule I as proposed.

Taking into account the scientific and medical evaluations and recommendations of the Acting Assistant Secretary for Health, the recently enacted Anti-Drug Abuse Act of 1986 (Pub. L. 99-570) and his own evaluations in accordance with the provisions of 21 U.S.C. 811(c), the Administrator of the Drug Enforcement Administration, pursuant to the provisions of 21 U.S.C. 811(a) and 811(b) finds that:

(1) Finalization of rules applicable to the scheduling of tiletamine and zolazepam as individual entities is not warranted at this time. Neither tiletamine nor zolazepam, as discrete substances, is perceived to pose a significant threat to the health and general welfare at this time. Neither substance has been encountered in the illicit trade and neither is available as a commercial product. In addition, persons engaged in activities prohibited by the CSA can be prosecuted if those activities involve tiletamine, pursuant to sections 102(32) and 203 of the Controlled Substances Act [21 U.S.C. 802(32) and 813], as amended by section 1201 of the Anti-Drug Abuse Act of 1986. Tiletamine has a chemical structure and a pharmacological profile substantially similar to that of a substance in Schedule II; thus, tiletamine fulfills the criteria of a controlled substance analog. Zolazepam is not affected by the 1986 amendments; however, if zolazepam is encountered in the illicit trade and found to be an imminent hazard to the public safety, the substance can be added to Schedule I on an emergency basis pursuant to 21 U.S.C. 811(h) if there is no exemption or approval in effect under 21 U.S.C. 355. These considerations are taken so as to accommodate legitimate industry in the production and marketing of a Food and Drug Administration approved drug product.

(2) Practical enforcement considerations necessitate that all mixtures of tiletamine and zolazepam be treated alike under the CSA. This will be re-evaluated if changes occur in the status under the CSA of the individual substances.

(3) In relation to mixtures of tiletamine, zolazepam and salts thereof, the Administrator finds that:

(a) Mixtures of tiletamine and zolazepam have a potential for abuse less than the drugs or other substances in Schedules I and II.

(b) Certain mixtures of tiletamine and zolazepam have an accepted medical use in treatment in the United States.

(c) Abuse of mixtures of tiletamine and zolazepam may lead to moderate or low physical dependence or high psychological dependence.

The above findings are consistent with placement of tiletamine-zolazepam mixtures into Schedule III of the CSA. The effective date of the rule will be February 20, 1987. In the event this imposes special hardship on any registrant, the Drug Enforcement Administration will entertain any justified request for an extension of time to comply with the Schedule IV regulations. The applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports tiletamine-zolazepam mixtures or who engages in research or conducts instructional activities with respect to such mixtures, 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.* Each tiletamine-zolazepam mixture must be stored in accordance with §§ 1301.71 through 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and packaging.* All labels and labeling for commercial containers of tiletamine-zolazepam mixtures must comply with the requirements of §§ 1302.03 through 1302.05 and 1302.08 of Title 21 of the Code of Federal Regulations.

4. *Inventory.* Every registrant required to keep records who possesses any quantity of a tiletamine-zolazepam mixture shall take inventories, pursuant to §§ 1304.11 through 1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of such mixtures.

5. *Records.* All registrants required to keep records pursuant to §§ 1304.21 through 1304.27 of Title 21 of the Code of Federal Regulations shall do so regarding tiletamine-zolazepam preparations or mixtures.

6. *Prescriptions.* All prescriptions of products containing tiletamine and zolazepam shall comply with §§ 1306.01 through 1306.06 and §§ 1306.21 through 1306.25 of Title 21 of the Code of Federal Regulations.

7. *Importation and exportation.* All importation and exportation of tiletamine-zolazepam mixtures shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

8. *Criminal liability.* The Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to tiletamine-zolazepam mixtures 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 Administrator certifies that the placement of commercial products which contain tiletamine and zolazepam into Schedule III of the Controlled Substances Act will not have a significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). Commercial products which contain tiletamine and zolazepam will be used in venterinary clinics. This rule will cause such establishments to handle these products in a manner indetical to that already used in relation to other Schedule III products.

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 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 (46 FR 13193).

#### List of Subjects in 21 CFR Part 1308

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

Pursuant to the authority vested in the Attorney General by section 201(a) of the Controlled Substances Act [21 U.S.C. 811(a)] as redelegated to the Administrator of the Drug Enforcement Administration by 28 CFR 0.100 and for the reasons set forth above, the Administrator hereby orders Part 1308, Title 21, Code of Federal Regulations, be amended 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).

2. Paragraph (c) of 1308.13 is amended by adding a new subparagraph (c)(12), reading as follows:

#### § 1308.13 Schedule III

(c) Depressants. . . .

(12) Tiletamine and zolazepam or any salt thereof—7295.

Some trade or other names for a tiletamine-zolazepam combination product: Telazol.

Some trade or other names for tiletamine: 2-(ethylamino)-2-(2-thienyl)-cyclohexanone.

Some trade or other names for zolazepam: 4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-[3,4-e] [1,4]-diazepin-7(1H)-one. flupyrazapon.

Dated: January 12, 1987.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 87-1218 Filed 1-20-87; 8:45 am]

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#### DEPARTMENT OF THE TREASURY

#### Bureau of Alcohol, Tobacco and Firearms

#### 27 CFR Parts 19 and 250

[T.D. ATF-233; correction]

#### Implementing the Caribbean Basin Recovery Act; Distribution of Excise Taxes on Imported Rum; Correction

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Final rule (Treasury decision); correction.

**SUMMARY:** This document corrects a printing error made in FR Doc. 86-17440, published in the *Federal Register* on August 5, 1986, at 51 FR 28071, which implemented the Caribbean Basin Recovery Act; Distribution of Excise Taxes on Imported Rum.

**FOR FURTHER INFORMATION CONTACT:** Jackie White, Distilled Spirits and Tobacco Branch, (202) 566-7531.

#### SUPPLEMENTARY INFORMATION: Paragraph 1

In the left-hand column on page 28078 in the twelfth line of § 250.31(b) replace "87.62889" with "87.626889".

Signed: January 14, 1987.

Stephen E. Higgins,

Director.

[FR Doc. 87-1205 Filed 1-20-87; 8:45 am]

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