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 Department 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 new paragraphs (b)(31) and (b)(39), and redesignating the existing paragraphs (b)(31) through (b)(37) and (b)(38) through (b)(46) as (b)(32) through (b)(46) and (b)(40) through (b)(48), respectively:

§ 1308.11 Schedule I.

(b) * * * * *

(31) 1-methyl-4-phenyl-4-propionoxy-
piperidine (MPPP) .............................. 9661

(39) 1-(2-phenethyl)-4-phenyl-4-acetoxy-
piperidine (PEPAP) ............................. 9663

Dated: August 5, 1986.

John C. Lawn,
Administrator, Drug Enforcement Administration.

[FR Doc. 86-17949 Filed 8-8-86; 8:45 am]

BILLING CODE 4410-09-M

21 CFR Part 1308

Schedules of Controlled Substances; Placement of Tiletamine and Zolazepam into Schedule I and the Placement Of Certain Preparations Which Contain Both Tiletamine and Zolazepam into Schedule III

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. It proposes the placement of the substances, tiletamine and zolazepam, into Schedule I of the Controlled Substances Act and the placement of preparations which contain equal amounts of both tiletamine and zolazepam into Schedule III. This action reinstates an action which was proposed in 1980 and not completed. The effect of this action is to facilitate the marketing of a veterinary pharmaceutical product and to discourage the abuse of the product and the individual ingredients.

DATE: Comments must be submitted on or before September 10, 1986.

ADDRESS: Comments and objections should be submitted in quintuplicate 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, Washington, DC 20537. Telephone: (202) 633-1306.

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 1308

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

A proposed rule was published in the Federal Register on July 9, 1981 (46 FR 35529-35531), proposing that the substances, tiletamine and zolazepam, be placed into Schedule I and that preparations containing equal weights of both be placed into Schedule III of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). The action was initiated in response to a letter from the then Acting Assistant Secretary for Health, Department of Health and Human Services, which recommended that tiletamine and zolazepam be placed into Schedule III when the Food and Drug Administration (FDA) approved the new Animal Drug Application (NADA) for Telazol®. Enclosed with the letter from the Acting Assistant Secretary was a scientific and medical evaluation which listed the factors which the Act requires the Secretary to consider, and summarized the matters considered by the Acting Assistant Secretary in recommending the control of tiletamine, zolazepam and the veterinary product under the Controlled Substances Act. The factors considered by the Secretary for each entity were:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effects, if known.

(3) The state of current scientific knowledge regarding the drug or other substance.

(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.

(7) Its psychic or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under the Controlled Substances Act.

The Administrator, in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), has relied on the scientific and medical evaluations and the
recommendations of the Acting Assistant Secretary for Health, which were provided pursuant to section 201(f) of the Act [21 U.S.C. 811(f)].

Under 21 U.S.C. 811(a), the Administrator must apply the provisions of 21 U.S.C. 812 when considering whether to add a drug or other substance to a schedule. Title 21, United States Code, section 812(b) provides that a drug or other substance must have an accepted medical use in treatment in the United States in order that it be considered for placement into Schedules II, III, IV or V. That section also provides that a drug or other substance which has no currently accepted medical use in treatment in the United States be considered for placement into Schedule I.

The Administrator finds that approval of the NADA for the tiltemine-zolazepam combination product means that the product has an accepted medical use in treatment in the United States. The letter of the then Acting Assistant Secretary of Health was silent with respect to whether approval of the NADA confers accepted medical use status on the individual components of a veterinary combination product. However, the then Acting Director of the FDA Bureau of Veterinary Medicine specifically advised that neither of the ingredients, taken separately, had an acceptance in treatment in the United States. Currently neither tiltemine nor zolazepam is approved for marketing in the United States in single entity preparations for use in medical treatment.

Tiltemine, a chemical analog of phencyclidine (PCP), has pharmacological properties similar to that Schedule II substance. In addition, when administered alone, convulsive seizures and clonic muscular reactions result in some species of animals. When zolazepam is combined with tiltemine, the convulsive and clonic muscular reactions are absent. Currently there is no approved veterinary use for tiltemine as a single entity. Tiltemine is a hallucinogenic substance. In that PCP has been demonstrated to have a high potential for abuse, the Administrator finds in relation to the substance tiltemine, its salts, isomers, and salts of isomers that:

1. Tiltemine has a high potential for abuse.
2. Tiltemine has no currently accepted medical use in treatment in the United States.
3. There is a lack of accepted safety for use of tiltemine under medical supervision.

Zolazepam is chemically and pharmacologically related to chlordiazepoxide, diazepam and other benzodiazepines in Schedule IV. In addition, when administered alone, zolazepam produces bizarre behavioral reactions in some species of animals. When combined with tiltemine, the behavioral effects are absent. Acute lethality data indicate that zolazepam is considerably more toxic than the benzodiazepines which are currently available for use in medical treatment. Although zolazepam has not been tested in human subjects, nor have animal studies been conducted to precisely determine the relative abuse potential of the substance, zolazepam is chemically and pharmacologically similar to other benzodiazepines which have been subject to a considerable amount of abuse and have presented unexpectedly severe medical consequences when withdrawal is attempted. Unlike these other benzodiazepines, the toxicity of zolazepam is significantly greater, the substance has not been accepted for use as a single entity, and its safety for use under medical supervision has not been established. Therefore, the Administrator finds in relation to the substance, zolazepam, its salts, isomers, and salts of isomers that:

1. Zolazepam has a high potential for abuse.
2. Zolazepam has no currently accepted medical use in treatment in the United States.
3. There is a lack of accepted safety for use of zolazepam under medical supervision.

In 1982, the FDA Bureau of Veterinary Medicine (currently, the FDA Center for Veterinary Medicine) approved a NADA for a mixture of tiltemine hydrochloride and zolazepam hydrochloride for use as an anesthetic agent in dogs and cats. As the product has not been marketed, no data are available on actual human abuse. The abuse potential of the mixture was evaluated in animal studies and the then Acting Assistant Secretary found that the mixture has a potential for abuse less than the drugs or other substances in Schedules I and II. The pharmacological profile of the mixture is similar to that of PCP, and the data are consistent with the concept that the mixture will initiate and maintain self-administered behavior. The mixture was found to have positive reinforcing properties in drug-experienced rhesus monkeys, indicating that ingestion of the drug may produce high psychological dependence in humans. Unlimited access to the mixture resulted in a mild to moderate withdrawal syndrome in monkeys, indicating that the mixture produces moderate or low physical dependence.

The Administrator finds in relation to a mixture of equal weights of tiltemine and zolazepam and salts thereof that:

1. The above described mixture has a potential for abuse less than the drugs or other substances in Schedules I and II.
2. The above described mixture has an accepted medical use in treatment in the United States.
3. Abuse of the above described mixture may lead to moderate or low physical dependence or high psychological dependence.

Interested persons are invited to submit their comments or objections in writing regarding this proposal. If a person believes that one or more issues raised by him warrant a hearing, he should so state and summarize the reasons for his belief. In the event comments, objections or requests for a hearing received in response to this proposal raise one or more issues which warrant a hearing, the Administrator will publish in the Federal Register an order for a public hearing which will summarize the issues to be heard and set the time for the hearing that will not be less than 30 days after the date of the order. If no objections presenting grounds for a hearing on this proposal are received within the time limitation or if interested parties waive or are deemed to have waived their opportunity for a hearing or to participate in a hearing, the Administrator, after giving consideration to written comments and objections, will issue a final order pursuant to 21 CFR 1308.48 without a hearing.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the placement of tiltemine and zolazepam into Schedule I and the placement of commercial products which contain equal quantities of tiltemine 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). These proposed drug control actions relate to the initial control of two substances which are not marketed in the United States and to an approved product which may be used in medical treatment in the United States but which has not yet been marketed. Commercial products with contain tiltemine and zolazepam will be used in veterinary clinics. This rule, if finalized, will cause such establishments to handle products which contain tiltemine and zolazepam in a manner identical to that already
used in relation to other Schedule III products.

In accordance with the provisions of 21 U.S.C. 811(a), this proposal to place
tiletame and zolazepam into Schedule I and certain preparations thereof into
Schedule III, is a formal rulemaking "on the record after opportunity for a
hearing." Such proceedings are

28 CFR 0.100, and for the reasons set forth
above, the Administrator hereby
proposes to amend 21 CFR Part 1308 as follows:

PART 1308—AMENDED

1. The authority citation for 21 CFR
Part 1308 continues to read as follows:

2. Paragraph (d) of § 1308.11 is
amended by adding a new subparagraph
(25) to read as follows:

§ 1308.11 Schedule I.

(d) Hallucinogenic substances.

(25) Tiletame. 7290
Some trade or other names: 2-
(ethylamino)-2-(2-thienyl) cyclohexaneone.

3. Paragraph (e) of § 1308.11 is
amended by adding a new subparagraph
(3) to read as follows:

§ 1308.11 Schedule I.

(e) Depressants.

(3) Zolazepam. 2930
Some trade or other names: 4-(o-
fluorophenyl)-6,8-dihydro-1,3,8-
trimethylpyrazole-[3,4-e] [1,4]-
diazepin-7(1H)One.

4. Paragraph (c) of § 1308.1 is
amended by redesignating the existing
paragraphs [c][4] through [c][11] as [c][5]
through [c][12] and adding a new
paragraph [c][4], reading as follows:

§ 1308.13 Schedule III.

(c) Depressants.

(4) Any compound, mixture or pre-
paration containing equal weights of both tiletamine and zolazepam or any salt thereof and not mixed with
other psychoactive sub-
stances. 7295

Dated: August 5, 1986.
John C. Lawa,
Administrator, Drug Enforcement Administration.

[FR Doc. 86-17990 Filed 8-8-86; 8:45 am]
BILLING CODE 4410-05-M

DEPARTMENT OF THE INTERIOR
Office of Surface Mining Reclamation and Enforcement

30 CFR Part 915

Public Comment Procedures and
Opportunity for Public Hearing on
Proposed Modifications to the Iowa
Permanent Regulatory Program Under
the Surface Mining Control and
Reclamation Act of 1977

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Proposed rule.

SUMMARY: OSMRE is announcing
procedures for a public comment period
and for requesting a public hearing on
the substantive adequacy of a program
amendment submitted by Iowa as an
amendment to the State's permanent
regulatory program (hereinafter referred
to as the Iowa program) under the
Surface Mining Control and Reclamation
Act of 1977 (SMCRA).

The amendment submitted by letter
dated June 16, 1986, consists of proposed
changes that reorganize Iowa's State
government. The proposed amendment
would transfer all of the functions of
Iowa's Department of Soil Conservation—including coal regulation and
abandoned mine lands—to the
newly created Division of Soil
Conservation in the Iowa Department of
Agriculture and Land Stewardship.

This notice sets forth the times and
locations that the Iowa program and the
proposed amendment will be available
for public inspection, the comment
period during which interested persons
may submit written comments on the
proposed amendment, and the
procedures that will be followed for the
public hearing.

DATES: Written comments from the
public not received by 4:30 p.m.,
September 10, 1986 will not necessarily
be considered in the decision on
whether the proposed amendment
should be approved and incorporated
into the Iowa regulatory program. If
requested, a public hearing on the
proposed amendments has been
scheduled for September 1, 1986. Any
person interested in speaking at the
hearing should contact Mr. William J.
Kovacич at the address or telephone
to the Minnesota listed below by August 28, 1986. If
no person has contacted Mr. Kovacич
by that date to express an interest in the
hearing, the hearing will be cancelled. If
only one person requests an opportunity
to speak at the public hearing, a public
meeting, rather than a hearing, may be
held and the results of the meeting

ADDITIONAL INFORMATION:

1. Background to the Iowa Program

The Iowa program was conditionally
approved by notice published in the
January 21, 1981 Federal Register (48 FR