DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 157 and 375

[Docket Nos. RM81-19 and RM81-29]

Blanket Certification of Routine Gas Pipeline Transactions; Availability of Environmental Assessment

July 1, 1981.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Availability of Environmental Assessment.

SUMMARY: Notice is hereby given in Docket Nos. RM81-19 and RM81-29 that on July 6, 1981, the Federal Energy Regulatory Commission (FERC) made available to the public an environmental assessment (EA) evaluating the proposed rules issued on March 10 and April 27, 1981 (46 FR 16903 and 24585). These rulemakings would create a more efficient certification procedure for routine natural gas pipeline transactions by creating two new categories of transactions. One category would involve no action or review by the Commission. A second category would require Commission action only if a protest were filed following notice of the proposed transaction in the Federal Register. All other transactions would continue to be filed under the current procedures requiring detailed analysis by the Commission. Implementation of the proposed rules would enable the Commission to focus more closely on those filings and issues which truly merit Commission attention.

The EA concludes that implementation of the rules would not constitute a major Federal action significantly affecting the quality of the human environment.

DATE: The Commission invites all interested parties to file comments on this EA on or before August 10, 1981.

ADDRESS: File comments with: Kenneth F. Plumb, Secretary, FERC, 825 N. Capitol Street, NE, Washington, D.C. 20426.

This EA has been placed in the FERC's public files and is available for public inspection in the FERC's Office of Congressional and Public Affairs, Room 1000, 825 North Capitol Street, NE, Washington, D.C. 20426. Copies are available in limited quantities upon request.

FOR FURTHER INFORMATION CONTACT: Requests for further information should be addressed to Mr. John S. Loess, Project Manager, FERC, Room 7102, 825 North Capitol Street, NE, Washington, D.C. 20426; telephone (202) 357-9038.

Kenneth F. Plumb,
Secretary.

[FR Doc. 81-20715 Filed 7-6-81; 8:45 am]
BILLING CODE 6450-45-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Placement of Tiletamine and Zolazepam Into Schedule I and the Proposed 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 was initiated upon the receipt of a letter from the Acting Assistant Secretary for Health. The effect of this proposed action will be to discourage the abuse of tiletamine and zolazepam.

DATE: Comments must be submitted on or before (sixty days from date of publication).

ADDRESS: Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, 1405 I Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Howard McClain Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 353-1366.

SUPPLEMENTARY INFORMATION: On March 29, 1981, the Administrator of the Drug Enforcement Administration received a letter from the Acting Assistant Secretary for Health, acting on behalf of the Secretary of the Department of Health and Human Services, recommending that tiletamine and zolazepam be placed into Schedule III of the Controlled Substances Act (21 U.S.C. 801 et seq.). If and when the New Animal Drug Application for Telazol is approved by the Food and Drug Administration. Enclosed with this letter was a document which listed the factors which the Act requires the Secretary to consider and the summarized considerations of the Secretary in recommending control for tiletamine and zolazepam. The letter of the Acting Assistant Secretary is set forth below:

March 29, 1981.

Mr. Peter B. Bensinger,
Administrator, Drug Enforcement Administration, 1405 I Street, NW., Washington, D.C. 20537

Dear Mr. Bensinger:

Pursuant to the Controlled Substances Act, 21 U.S.C. 811(f), this letter is notification that the Department of Health and Human Services believes that the drugs tiletamine HCl and zolazepam have abuse potential. Under the definitions of the Controlled Substances Act, tiletamine HCl is a hallucinogen and zolazepam HCl is a depressant. Tiletamine HCl, a dissociative anesthetic, and Zolazepam HCl, an anticonvulsant benzodiazepine, are the components of Telazol®, a veterinary drug product which is pending approval for marketing by the Food and Drug Administration. I have enclosed our consideration of the factors listed in Section 201(c) of the Controlled Substances Act and our recommendation.

I concur with the Food and Drug Administration's recommendation that tiletamine HCl substance and zolazepam substance be controlled under the provisions of Schedule III of the Controlled Substances Act. I further recommend that these scheduling actions become effective if and when the New Animal Drug Application (NADA) for Telazol® has received final approval from the Food and Drug Administration.

Should you have any questions concerning this recommendation, the appropriate staff is prepared to respond.

Sincerely yours,

Charles Miller.

Acting Assistant Secretary for Health.

Enclosure: Basis for Recommendation for Control of Tiletamine and Zolazepam.

Relying on the scientific and medical evaluation of the Acting Assistant Secretary for Health and based on his independent evaluation in accordance with the provisions of 21 U.S.C. 811(c), the Administrator of the Drug Enforcement Administration finds that:

The Acting Assistant Secretary for Health has found that the substances, tiletamine and zolazepam and the drug product, Telazol®, each have an abuse potential. Telazol®, if approved by the Food and Drug Administration, will be composed of equal amounts of the base equivalents of tiletamine and zolazepam. If the New Animal Drug Application (NADA) for this drug product, Telazol® is approved, the simultaneous use of equal amounts of tiletamine and zolazepam will have a
currently accepted medical use in the United States. The Acting Assistant Secretary for Health has not informed the Administrator that the approval of the NADA for "Tolazolo® will confer current medical use status on the individual components of the combination product. Currently, neither tiletamine nor zoletil is approved for marketing in the United States in single entity preparations for use in medical treatment.

In accordance with 21 U.S.C. 811(a), the Administrator must apply the provisions of 21 U.S.C. 812 in ruling to add a drug or other substance to a schedule. 21 U.S.C. 812(b) provides that a drug or other substance have an accepted medical use in treatment in the United States in order that it be considered for placement into Schedules I, II, III, IV or V. 21 U.S.C. 812(b) also provides that a drug or other substance which has not currently accepted medical use in treatment in the United States be considered for placement into Schedule I.

If the Food and Drug Administration acts favorably in respect to the pending NADA, the Schedule III criterion (21 U.S.C. 812(b)(6)(D)) which specifies that a drug or other substance have a currently accepted medical use in treatment will be satisfied in respect to a preparation which is composed of equal weights of the base equivalents of tiletamine and zoletil. The Schedule III criterion will not be satisfied in relation to the individual substances, tiletamine and zoletil or in relation to preparations which contain other than equal amounts of the base equivalents of tiletamine and zoletil.

Tiletamine is a chemical analog of phencyclidine (PCP) and has pharmacological properties similar to those of PCP. In that PCP has been demonstrated to have a high potential for abuse, the Administrator finds in relation to the substance, tiletamine, [2-(ethylamino)-2-(2-thienyl)-cyclohexanone], its salts, isomers, and salts of isomers and that:

(1) Tiletamine has a high potential for abuse.

(2) Tiletamine has no currently accepted medical use in treatment in the United States.

(3) There is a lack of accepted safety for use of tiletamine under medical supervision.

Zoletil is chemically and pharmacologically related to chloridiazepoxide, diazepam and the other benzodiazepines in Schedule IV but differs in its acute lethality. Zoletil is considerably more toxic than the benzodiazepines which are currently available for use in medical treatment. Zoletil is not been tested in human subjects, nor have animal studies been conducted to elucidate the abuse potential of the substance. In that the toxicity of zoletil is significantly greater than that of the Schedule IV benzodiazepines, those properties which contribute to the abuse potential of zoletil may be more severe than those associated with the currently available benzodiazepines. Therefore, the Administrator finds in relation to the substance zoletil, [4-(6-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazole [3,4-e] [1,4]diazepin-7(1H)-one, its salts, isomers, and salts of isomers and that:

(1) Zoletil has a high potential for abuse.

(2) Zoletil has no currently accepted medical use in treatment in the United States.

(3) There is a lack of accepted safety for use of zoletil under medical supervision.

The abuse potential of a mixture of equal quantities of tiletamine and zoletil has been evaluated in animal studies. The mixture was found to have positive reinforcing properties in drug-experienced rhesus monkeys, indicating that ingestion of the drug may produce psychological dependence in humans. On completion of a 30-day period of unlimited access to the mixture, monkeys exhibited a mild to moderate withdrawal syndrome, indicating that the mixture produces physical dependence. The Administrator finds in relation to a mixture of equal amounts of the base equivalents of tiletamine and zoletil and salts thereof that:

(1) The above described mixture has a potential for abuse less than the drugs in Schedules I and II.

(2) The above described mixture will, upon approval of the New Animal Drug Applications by the Food and Drug Administration, have a currently 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.

Therefore, 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 Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR Part 0.100), the Administrator hereby proposes to revise 21 CFR 1308.11(d)(24), 1308.11(e)(3) and 1308.13(c)(4) through (13), to read as follows:

§ 1308.11 Schedule I.

(d) * * * * * * * * * * *

(24) Tiletamine (an analog of phencyclidine) ...2209
Some trade or other names: 2-ethylamino)-2-
[2-thienyl]-cyclohexanone
* * * * * * * * * * *

§ 1308.13 Schedule III.

(c) * * * * * * * * * * *

(9) Any compound, mixture or preparation containing
equal weights of the base equivalents of both
tiletamine and zoletil not mixed with other
psychoactive substances
7205
(6) Chloroform
2510
(6) Glutethimide
2550
(6) Ketamine or any salt thereof
7350
(6) Lysergic acid
7300
(6) Lysergic acid diethylamide
7310
(10) Methadone
2975
(11) Sufentanyl
2209
(12) Sufentanil
2209
(13) Subluna
2910
* * * * * * * * * * *

Interested persons are invited to submit their comments, objections or requests for hearing in writing with regard to this proposal. Requests for hearing should state with particularity the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, 1405 I Street, N.W., Washington, D.C. 20537, Attention: DEA Federal Register Representative.

In the event that comments, objections or requests for hearing raise one or more issues which the Administrator finds warrant a hearing, the Administrator shall order a public hearing by notice in the Federal Register, summarizing the issues to be heard and setting the time for the hearing which will not be less than 30 days after the date of the notice.

If no objections presenting grounds for a hearing on this proposal are received within the time limitation, or interested parties waive or are deemed to waive their opportunity for a hearing or to participate in a hearing, the Administrator, after giving consideration to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Commercial products which contain tiletamine and zoletil will be used in veterinary clinics. This rule, if finalized, will cause such establishments to handle products which contain.
DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD 81-044]

Drawbridge Operation Regulations; Mystic River

AGENCY: Coast Guard, DOT.

ACTION: Proposed Rule.

SUMMARY: At the request of the Massachusetts Bay Transportation Authority, the U.S. Coast Guard is considering amending the regulations governing the railroad drawspan across the Mystic River, mile 1.4, between Charlestown and Everett. The Coast Guard intends to include the City of Boston highway bridge at mile 1.4 in this proposal as existing regulations also apply to the highway bridge. The present regulations for both bridges permit the drawspans to be closed to navigation from 7:45 a.m. to 9 a.m., 8:10 a.m. to 10 a.m., and 5 p.m. to 6 p.m., except on Sundays and holidays if a vessel's draft is less than 18 feet. The drawspan must be opened at all other times. The proposed amendment would stipulate that the draws of these bridges would not open for the passage of any vessels regardless of size between 1 a.m. and 5 a.m., inclusive, and at 9 a.m. and 5 p.m., except on Sundays and on legal holidays observed in the locality. At all other times the draws will open hourly, on the hour, to permit waiting vessels to pass. A vessel or other watercraft which has passed through one drawbridge would be afforded continuous passage through the other. This action may accommodate the needs of railroad traffic while still providing for the reasonable needs of navigation.

DATE: Comments must be received on or before August 10, 1981.

ADDRESS: Comments shall be mailed to or hand-delivered to and will be available for inspection or copying at the office of the Commander, First Coast Guard District, 150 Causway Street, Boston, Massachusetts 02114.

FOR FURTHER INFORMATION CONTACT: William J. Naulty, Chief, Bridge Branch, First Coast Guard District, 150 Causway Street, Boston, Massachusetts 02114 (617-223-0645).

SUPPLEMENTAL INFORMATION: Interested persons are invited to participate in this proposed rulemaking by submitting written views, comments, data or arguments. Persons submitting comments should include their name and address, identify the bridge and give reasons for concurrence with or any recommended change in the proposal. Persons desiring acknowledgement that their comments have been received should enclose a stamped, self-addressed postcard or envelope.

The Commander, First Coast Guard District will evaluate all comments received and decide on the final course of action. The proposed regulations may be changed in light of comments received.

DRAFTING INFORMATION: The principal persons involved in drafting this proposal are: William J. Naulty, Chief, Bridge Branch, First Coast Guard District, and Lieutenant William B. O'Leary, Project Attorney, Assistant Legal Officer, First Coast Guard District.

Discussion of the Proposed Regulation

The greatest use of the waterway each year occurs during the boating season (May through October). There is almost no vessel movement along the waterway during the remaining 6 months. The commuter rail system operates 52 trains a day Monday through Friday, 31 trains on Saturday, and 24 trains on Sunday throughout the year. The number of drawspan openings averaged 18 a day during the 1980 boating season. The majority of these openings were requested between 6 a.m. and midnight.

The hours of commuter travel. The greatest concentration of openings occurred during weekends. The proposed amendment would provide a uniform schedule of 17 openings a day, Monday through Saturday. The proposal also provides that after midnight the drawspan may be closed until 6 a.m.

There would be no authorized closures on Sunday or on a holiday.

These proposed regulations have been reviewed under the provisions of Executive Order 12291 and have been determined not to be a major rule. In addition, these proposed regulations are considered to be nonsignificant in accordance with guidelines set out in the Policies and Procedures for Simplification, Analysis, and Review of Regulations (D.O.O Order 2100.5 of 5–22–80). An economic evaluation has not been conducted since, for the reasons discussed above, its impact is expected to be minimal. In accordance with § 605(b) of the Regulatory Flexibility Act (94 Stat. 1164), it is also certified that these rules, if promulgated, will not have a significant economic impact on a substantial number of small entities.

In consideration of the foregoing, it is proposed that Part 117 of Title 33 of the Code of Federal Regulations be amended by revising § 117.75 to read as follows:

§ 117.75 Boston Harbor, Mass., and Adjacent Waters; bridges.

(g) Mystic River—(1) Bridges from mouth to and including the railroad bridge between Charlestown and Everett. The draws of these bridges shall not be required to be open for the passage of vessels between 1 a.m. and 5 a.m. inclusive, and at 9 a.m. and 5 p.m. except on Sundays and on legal holidays observed in the locality. At all other times the draws will open hourly, on the hour, to permit waiting vessels to pass. A vessel or other watercraft proceeding either upstream or downstream which has passed any of these bridges shall be afforded continuous passage through the succeeding bridges.

(33 U.S.C. 499; 49 U.S.C. 1655(g)(2); 49 CFR 1.46(c)(5); 33 CFR 1.05–4(g)(3))

R. H. Wood, Rear Admiral, Coast Guard, Commander, First Coast Guard District.

[FR Doc. 81-13981 Filed 7-8-81; 8:15 am]

BILLING CODE 4910-14-M