

Manufacturer or supplier	Product name and supplier's catalog no.	Form of product	Date of application
Do.	OMEGA Ligand Control Serum I.	do.	Feb. 24, 1981.
Do.	OMEGA Ligand Control Serum II.	do.	Do.
Do.	OMEGA Ligand Control Serum III.	do.	Do.
Industrial Optical	Opti-Neon	Bottle: 5 gal.	June 24, 1981.
Kelco Labs, Inc.	Barbital Buffer, No. 601	Vial: 8.33 g.	May 19, 1981.
Do.	Quantical 125I-T3 Uptake Reagent	2 Glass Bottles: 110 ml.	June 24, 1981.
Do.	Quantical 125I-T3 Uptake Kit, Cat. No. 833	Kit: 100 tests	Do.
Research Triangle Institute	Iodine Kit for Radioimmunoassay of delta-9 THC in Blood	Kit cts: 22—1 ml vials, 2—20 ml vials, 2—250 ml vials	July 10, 1981.
Do.	Delta-9 THC Plasma Standards Kit	Kit cts: 12—2 ml ampuls, 1—5 ml ampul	Feb. 18, 1981.
SIGMA Chemical Co.	D-amphetamine sulfate, product no. A-3278	Vial: 1 ml.	May 11, 1981.
Do.	Cannabitol, product no. C-6335	do.	Do.
Do.	Cannabitol, product no. C-6520	do.	Do.
Do.	NH-Dichloropentamine, product no. D-0332	do.	Do.
Do.	Mephobarbital, product no. M-3514	do.	Do.
Do.	Phenylacetone, product no. P-2024	do.	Do.
Do.	Phenmetrazine, product no. P-3524	do.	Do.
Do.	Tropacocaine, product no. T-4516	do.	Do.
Do.	1-Tetrahydrocannabinol, product no. T-4764	do.	Do.
Do.	6-Tetrahydrocannabinol, product no. T-4833	do.	Do.
E. R. Squibb & Sons, Inc.	Digoxin Premix, H0340	Bottle: 200 ml.	Mar. 20, 1981.
Do.	Digoxin Antiserum (Rabbit), H0340	Bottle: 100 ml.	Do.
SYVA Co.	Emul-el Serum Phenobarbital Positive Control	Vial: 3 ml.	June 1, 1981.
Do.	Emul-el Serum Phenobarbital Calibrator	do.	Do.
Do.	Emul-el Serum Phenobarbital Assay	Vial: 3 ml, 60 vials/kit	Do.
Do.	Emul-el Serum Barbiturate Assay	do.	Feb. 16, 1981.
Do.	Emul-el Serum Phenylephrine Assay	do.	Do.
Do.	Emul-el Serum Calibrator	Vial: 3 ml.	Do.
Do.	Emul-el Serum Benzodiazepine Assay	Vial: 3 ml, 60 vials/kit	Do.
Do.	Emul-el Serum Controls	Vial: 3 ml, 2 vials/kit	Do.

[FR Doc. 81-31433 Filed 10-29-81; 6:45 am]

BILLING CODE 4410-09-M

21 CFR Part 1308**Schedules of Controlled Substances
Placement of Halazepam in Schedule IV****AGENCY:** Drug Enforcement Administration, Justice.**ACTION:** Final rule.

SUMMARY: This is a final rule placing the drug, halazepam, into Schedule IV of the Controlled Substances Act. As a result of this rule, halazepam will be subject to the manufacturing, distribution, dispensing, importation and exportation controls of Schedule IV.

EFFECTIVE DATE: October 29, 1981.

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

SUPPLEMENTARY INFORMATION: A notice was published in the Federal Register on Wednesday, April 29, 1981 (46 FR 23953-4), proposing that halazepam be placed into Schedule IV of the Controlled Substances Act (21 U.S.C. 801 *et seq.*). All persons were given until June 29, 1981 to submit any comments or objections in writing regarding this proposal. One comment was received from the American Society for Hospital Pharmacists (ASHP), which supported the placement of halazepam in Schedule IV. No other comments or objections

were received in response to this proposal, nor were there any requests for a hearing.

Relying on the scientific and medical evaluation and recommendation 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 Acting Administrator of the Drug Enforcement Administration, pursuant to the provisions of 21 U.S.C. 811(a) and 811(b), finds that:

(1) Based on information now available, halazepam has a low potential for abuse relative to the drugs or other substances listed in Schedule III;

(2) Halazepam has a currently accepted medical use in treatment in the United States; and,

(3) Abuse of halazepam may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

The above findings are consistent with the placement of halazepam into Schedule IV of the Controlled Substances Act.

This control action involves the initial scheduling of a substance not previously approved for marketing in the United States and is necessary for final marketing approval. In order to avoid delays in the initial marketing of halazepam which may cause economic

problems for the manufacturer, the control of halazepam will be effective on the date of publication of this final order. Further, all regulations applicable to Schedule IV substances will be effective on the date of publication. In the event this imposes special hardships on any registrant, the Drug Enforcement Administration will entertain any justified requests for an extension of time to comply with the Schedule IV regulations.

1. **Registration.** Any person who manufactures, distributes, imports or exports halazepam or who engages in research or conducts instructional 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.** Halazepam 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 halazepam must comply with the requirements of §§ 1302.03-1302.05 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 halazepam must take inventories pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of these substances on hand.

5. **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 halazepam.

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

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

8. **Criminal Liability.** The Acting Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to halazepam not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful.

**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 0.100), the Acting Administrator hereby orders that 21 CFR 1308.14(c)(11)-(22) be revised to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(11) Halazepam.....	2762
(12) Lorazepam.....	2885
(13) Mebutamate.....	2800
(14) Meproamate.....	2820
(15) Methohexital.....	2264
(16) Methylphenobarbital (mephobarbital).....	2250
(17) Oxazepam.....	2835
(18) Paraldehyde.....	2585
(19) Petrichloral.....	2591
(20) Phenobarbital.....	2285
(21) Prazepam.....	2764
(22) Temazepam.....	2925

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The Food and Drug Administration issued a letter on September 24, 1981, notifying the Schering Corporation of the final approval of their New Drug Application for halazepam. A copy of this letter was received by DEA. The notification further stated that halazepam may not be legally marketed until a final order placing halazepam into Schedule IV of the CSA by the Drug Enforcement Administration is published in the Federal Register.

Pursuant to 5 U.S.C. 805(b), the Acting Administrator certifies that the placement of halazepam into Schedule IV 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). This action involves the initial control of a substance not previously approved for marketing in the United States.

In accordance with the provisions of 21 U.S.C. 811(a), this placement of halazepam into Schedule IV 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).

Dated: October 23, 1981.

Francis M. Mullen, Jr.,
Acting Administrator, Drug Enforcement Administration.

[FR Doc. 81-31439 Filed 10-28-81; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF DEFENSE

Corps of Engineers, Department of the Army

33 CFR Part 209

Administrative Procedures; Shipping Safety Fairways and Anchorages, Gulf of Mexico

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Army is eliminating the Mermentau Pass Safety Fairway by revoking 33 CFR 209.135(d)(17). The fairway no longer serves its intended purpose and removal of this restriction will allow for further oil and gas exploration in the area.

EFFECTIVE DATE: November 30, 1981.

ADDRESS: HQDA, DAEN-CWO-N, Washington, D.C. 20314.

FOR FURTHER INFORMATION CONTACT: Mr. Charles Decker at (504) 838-2255 or Mr. Ralph T. Eppard at (202) 272-0200.

SUPPLEMENTARY INFORMATION: Shipping safety fairways and anchorage areas were established by the Department of the Army to provide safe approaches through oil fields in the Gulf of Mexico to entrances to the major ports along the coast. The regulations which establish these fairways in 33 CFR 209.135 were approved by the Secretary of the Army on 18 December 1968 and last amended on 10 February 1981. The Department of the Army is now amending fairway regulations by deleting paragraph (d)(17) to disestablish the Mermentau Pass Safety Fairway. The proposed change was published in the Notice of Proposed Rulemaking Section of the Federal Register on 2 July 1981 (46 FR 34583) with the comment period expiring on 3 August 1981. We received no comments. Shoaling in the area of the Mermentau Pass Safety Fairway has reduced the water depth and as a result, deep draft vessels no longer travel in the area. Vessel traffic now gains access to the Gulf of Mexico via a channel dredged and maintained from Lower Mud Lake by the Corps of Engineers. Elimination of this fairway would allow for further oil and gas exploration. This matter has been coordinated with the U.S. Coast Guard. The Army is also taking this opportunity to remove an obsolete reference to the U.S. Naval Oceanographic Office and replace it with "Defense Mapping Agency Hydrographic Center."

Note.—The Department of the Army has determined that this document does not contain a major rule requiring a regulatory impact analysis under Executive Order 12291

because it will not result in an annual effect on the economy of \$100 million or more and it will not result in a major increase in costs or prices. The Department of the Army has also determined that this rule will not have a significant economic impact on a substantial number of entities and thus does not require the preparation of a regulatory flexibility analysis.

Accordingly, the Department of the Army is amending 33 CFR 209.135 by revising paragraph (b)(2)(v) and by removing and reserving paragraph (d)(17) as set forth below.

§ 209.135 Shipping Safety Fairways and Anchorage Areas, Gulf of Mexico.

* * * * *

(b) Permits.

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(2) * * *

(v) The permittee must notify the District Engineer, U.S. Geological Survey, Bureau of Land Management, U.S. Coast Guard, National Oceanic and Atmospheric Administration and the Defense Mapping Agency Hydrographic Center of the approximate dates (commencement and completion) the anchors will be in place to insure maximum notification of mariners.

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(d) The Areas.

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(17) [Reserved]

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(33 U.S.C. 403 and 43 U.S.C. 1333(e))

Dated: September 29, 1981.

William R. Gianelli,
Assistant Secretary of the Army (Civil Works).

[FR Doc. 81-31434 Filed 10-28-81; 8:45 am]

BILLING CODE 3710-92-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-4-FRL-1939-3]

Alabama: Revisions to Chapter 6 of the Alabama Rules and Regulations and Kentucky: Bubble Action for Corning Glassworks-Danville, Kentucky Plant; Approval and Promulgation of Implementation Plans

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA today approves changes in the Alabama and Kentucky State Implementation Plans (SIPs).

On April 1, 1981 the Alabama Air Pollution Control Commission (AAPCC) submitted to EPA revisions to Chapter 6