

Substances Act (21 USC 802(14)), the Drug Enforcement Administration will entertain any justified requests for extensions of time submitted to it on or before the required date of compliance.

4. Inventory. Every registrant required to keep records, who possesses any quantity of pipradrol or SPA, shall take an inventory, pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of these substances on hand on December 1, 1980.

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 pipradrol and SPA commencing on the date on which the inventories of these substances are taken.

6. Importation and Exportation. All importation and exportation of pipradrol and SPA on and after December 1, 1980, shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

7. Criminal Liability. The Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to pipradrol and SPA not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after December 1, 1980, shall be unlawful, except that any person who is not now registered to handle these substances but who is entitled to registration under such Acts may continue to conduct normal business or professional practice with these substances between the date on which this Rule is published and the date which he obtains or is denied registration; provided, that the application for such registration is submitted on or before December 1, 1980.

Dated: September 19, 1980.

Peter B. Bensinger,
Administrator, Drug Enforcement
Administration.

Under the authority vested in the Attorney General by Section 102(c) of the Psychotropic Substance Act of 1978 (21 U.S.C. 812), and delegated to the Administrator of the Drug Enforcement Administration pursuant to Sec. 0.100 of Title 28 of the Code of Federal Regulations, the Administrator hereby orders that Title 21 of the Code of Federal Regulations be amended by adding (e) (4) and (5) to § 1308.14:

§ 1308.14 Schedule IV.

* * * * *
(e) * * *

- (4) pipradrol, 1750.
(5) SPA ((-)-1-dimethylamino-1,2-diphenylethane), 1635.

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21 CFR Part 1308

Placement of Sufentanil and Tilidine in
Schedule I; Schedules of Controlled
Substances

AGENCY: Drug Enforcement
Administration, Department of Justice.
ACTION: Final rule.

SUMMARY: This is a Final Rule issued by the Administrator of the Drug Enforcement Administration placing sufentanil and tilidine in Schedule I of the Controlled Substances Act of 1970. This action is required in order for the United States to discharge its obligations under the Single Convention on Narcotic Drugs, 1961.

DATE: EFFECTIVE DATE OF CONTROL: December 1, 1980, except as otherwise provided in the SUPPLEMENTARY INFORMATION section of this rule.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: 202-633-1366.

SUPPLEMENTARY INFORMATION: By a letter dated April 17, 1980, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs has decided that the drugs, sufentanil and tilidine, be added to Schedule I of the Single Convention on Narcotic Drugs, 1961.

Section 201(d)(1) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 USC 811(d)) states that, if control of a substance is required by United States obligations under the Single Convention on Narcotic Drugs, "the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings and procedures required by section 201 (a) and (b) (21 USC 811 (a) and (b)) and section 202(b) (21 USC 812(b)) of the Act." This responsibility has been delegated to the Administrator of the Drug Enforcement Administration pursuant to § 0.100 of Title 28 of the Code of Federal Regulations.

In order to meet the obligations of the Single Convention on Narcotic Drugs and because sufentanil and tilidine have no currently accepted medical use, the Administrator of the Drug Enforcement

Administration has determined that these substances should be placed in Schedule I of the Controlled Substances Act.

EFFECTIVE DATES: 1. Registration. Any person who manufactures, distributes, imports, or exports sufentanil or tilidine, or who engages in research or conducts instructional activities with respect to these substances, or who proposes to engage in such activities, shall submit an application for registration to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations on or before December 1, 1980.

2. Security. Sufentanil and tilidine must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a), 1301.72(c)-(d), 1301.73, 1301.74(a)-(c), 1301.74(e)-(f), 1301.75(a), 1301.75(c), and 1301.76 of Title 21 of the Code of Federal Regulations on or before December 29, 1980. In the event this effective date imposes special hardships, the Drug Enforcement Administration will entertain any justified requests for extensions of time submitted to it on or before the required date of compliance.

3. Labeling and Packaging. All labels and labeling for commercial containers of sufentanil and tilidine, packaged after December 1, 1980, shall comply with the requirements of §§ 1302.03-1302.05 and 1302.07-1302.08 of Title 21 of the Code of Federal Regulations. In the event this effective date imposes special hardships on any "manufacturer," as defined in Section 102(14) of the Controlled Substances Act (21 USC 802(14)), the Drug Enforcement Administration will entertain any justified requests for extensions of time submitted to it on or before the required date of compliance.

4. Quotas. All persons required to obtain quotas for sufentanil and tilidine shall submit applications for calendar year 1981 pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations on or before December 1, 1980.

5. Inventory. Every registrant required to keep records, who possesses any quantity of sufentanil or tilidine, shall take an inventory, pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of sufentanil and tilidine on hand on December 1, 1980.

6. 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 sufentanil and tilidine commencing on the date on which the inventories of these substances are taken.

7. Reports. All registrants required to file reports on sufentanil and tilidine with the Drug Enforcement Administration pursuant to §§ 1304.37-1304.41 of Title 21 of the Code of Federal Regulations shall report on the inventory taken under paragraph 5 above and on all subsequent transactions.

8. Order Forms. Each distribution of sufentanil and tilidine on or after December 1, 1980, shall utilize an order form pursuant to Part 1305 of Title 21 of the Code of Federal Regulations.

9. Importation and Exportation. All importation and exportation of sufentanil and tilidine on and after December 1, 1980 shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

10. Criminal Liability. The Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to sufentanil and tilidine not authorized by, or in violation of, the controlled substances Act or the Controlled Substances Import and Export Act, conducted after December 1, 1980, shall be unlawful, except that any person who is not now registered to handle these substances but who is entitled to registration under such Acts may continue to conduct normal business or professional practice with these substances between the date on which this Rule is published and the date which he obtains or is denied registration; provided, that the application for such registration is submitted on or before December 1, 1980.

Dated: September 19, 1980.
 Peter B. Bensinger,
 Administrator, Drug Enforcement Administration.

Therefore, under the authority vested in the Attorney General by Section 201(d)(1) of the Controlled Substances Act (21 USC 812(d)(1)) and delegated to the Administrator of the Drug Enforcement Administration pursuant to § 0.100 of Title 28 of the Code of Federal Regulations, the Administrator hereby orders that §§ 1308.11(b) of Title 21 of the Code of Federal Regulations be amended as follows:

In § 1308.11, paragraph (b)(43) is redesignated as paragraph (b)(45) and new paragraphs (b)(43) and (b)(44) are added to read as follows:

§ 1308.11 Schedule I.

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- (b) * * *
- (43) Sufentanil, 9740.
- (44) Tilidine, 9750.

(45) Trimeperidine, 9646.

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21 CFR Part 1308
 Exempt Chemical Preparation
 Containing Controlled Substances

AGENCY: Drug Enforcement Administration.
 ACTION: Final rule.

SUMMARY: By this rule, the below listed chemical preparations and mixtures which contain controlled substances have, as indicated, either been added to or deleted from the list of exempt chemical preparations set forth in Title 21, Code of Federal Regulations, § 1308.24. Those which are included in the list are exempted from the application of various provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and from certain Drug Enforcement Administration regulations. This action is in response to DEA's periodic review of the exempt chemical preparation list and of applications for exemptions filed with DEA, and is consistent with the needs of researchers, chemical analysts, and suppliers of these products.

DATES: This rule is effective December 1, 1980, subject to being suspended, reinstated, revoked or amended by the Administrator upon consideration of any comments or objections timely filed on or before December 1, 1980, which raise significant issues on any finding of fact or conclusion of law supporting this rule.

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

SUPPLEMENTARY INFORMATION: The Administrator of the Drug Enforcement Administration has received applications pursuant to § 1308.23 of Title 21 of the Code of Federal Regulations (CFR) which ask that several chemical preparations

containing controlled substances be granted the exemptions provided for in 21 CFR 1308.24.

The Administrator hereby finds that each of the following chemical preparations and mixtures is intended for laboratory, industrial, educational, or special research purposes, is not intended for general administration to man or animal, and either (a) contains no narcotic controlled substances and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse, (b) contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration, that the preparation or mixture does not present any potential for abuse, or (c) the formulation of such preparation or mixture incorporates methods of denaturing or other means so that the controlled substance cannot in practice be removed, and therefore the preparation or mixture does not present any significant potential for abuse. The Administrator further finds that exemption of the following chemical preparations and mixtures is consistent with the public health and safety as well as the needs of researchers, chemical analysts and suppliers of these products.

Therefore, pursuant to the Act, the regulations of the Department of Justice and the Drug Enforcement Administration, the Administrator of the Drug Enforcement Administration hereby orders that Part 1308 of Title 21 of the Code of Federal Regulations be amended as hereinafter appears.

(Secs. 201, 202, 501(b), Controlled Substances Act, 21 U.S.C. 811, 812, 871(b)).

Dated: September 24, 1980.
 Peter B. Bensinger,
 Administrator.

a. Section 1308.24(i) is amended by deleting the following:

§ 1308.24 [Amended]
 (i) * * *

Manufacturer or supplier	Product name and supplier's catalog No.	Form of product	Date of application
Abbott Laboratories	Thyroscreen T, Diagnostic Kit	Kit: 500 tests, 100 tests, 50 tests.	July 6, 1977.
American Hospital Supply Corp. (Dade Division)	DATA-tope™ CT 125 4. Buffered 1 Thyroxine, Catalog No. B5644-21.	Bottle: 55 ml	June 11, 1975.
Do	DATA-tope™ CT 125 4. Buffered 1 Thyroxine, Catalog No. B5644-25.	Bottle: 255 ml	Do.
Do	DATA-tope™ T 125 4. Buffered 1 Thyroxine, Catalog No. B5644-29.	Bottle: 505 ml	Do.
Do	DATA-tope™ T 125 4. Buffered 1 Thyroxine, Catalog No. B5644-40.	Bottle: 55 ml	Do.
Do	DATA-tope™ T 125 4. Buffered 1 Thyroxine, Catalog No. B5644-45.	Bottle: 255 ml	Do.
Do	DATA-tope™ T 125 4. Buffered 1 Thyroxine, Catalog No. B5644-35.	Bottle: 505 ml	Do.
Millipore Corp.	(Delete this company and all products listed under it.)		
Millipore Corp. (Worthington Diagnostics Division)	(Delete this company and all products listed under it.)		