

diagnosis, treatment, and control of parasitism.

Effective date: May 25, 1984.
(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))
Dated: May 18, 1984.

Marvin A. Norcross,
Acting Associate Director for Scientific
Evaluation.

[FR Doc. 84-14028 Filed 5-24-84; 8:45 am]
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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Rescheduling of Sufentanil into Schedule II

AGENCY: Drug Enforcement
Administration, Justice.

ACTION: Final rule.

SUMMARY: This is a final rule removing sufentanil from Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*) and placing it into Schedule II. Sufentanil remains classified as a narcotic substance. As a result of this rule, sufentanil is subject to Schedule II narcotic controls, the majority of which are identical to those of Schedule I narcotics. In addition, sufentanil may be prescribed according to the CSA controls for Schedule II narcotic substances.

EFFECTIVE DATE: May 25, 1984.

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

SUPPLEMENTARY INFORMATION: A notice was published in the Federal Register on Tuesday March 20, 1984 (49 FR 10274), proposing that sufentanil, a narcotic substance, be transferred from Schedule I to Schedule II of the Controlled Substances Act. Interested persons were given until April 19, 1984, to submit comments or objections regarding the proposal. No comments or objections were received in response to the proposal; nor were there any requests for a hearing. In addition, according to a May 4, 1984 letter from Robert J. Temple, M.D., Acting Director, Office of Drug Research and Review, Center for Drugs and Biologics, Food and Drug Administration (FDA) of the Department of Health and Human Services, the New Drug Application (NDA) for sufentanil is approved; sufentanil is therefore safe and effective for use in medical treatment in the United States, as recommended by the FDA.

Based on the scientific and medical evaluation and recommendation of the Assistant Secretary for Health, on behalf of the Secretary, Department of Health and Human Services, sent on February 22, 1984 in accordance with section 201(b) of the CSA (21 U.S.C. 811(b)), the Administrator of the Drug Enforcement Administration, pursuant to Sections 201 (a) and (b) of the CSA (21 U.S.C. 811 (a) and (b)) finds that:

- (1) Sufentanil has a high potential for abuse.
- (2) Sufentanil has a currently accepted medical use in treatment in the United States.
- (3) Abuse of sufentanil may lead to severe psychological or physical dependence.

The above findings are consistent with placement of sufentanil into Schedule II of the CSA. Most of the regulations (for registration, security, labeling and packaging, quotas, inventory, records, reports, order forms, importation, exportation, and criminal liability) for Schedule II narcotic substances are the same as for Schedule I narcotic substances. Regulations that are effective on May 25, 1984 and imposed on sufentanil by this order are as follows:

1. **Registration.** Any person who manufactures, distributes, engages in research, imports or exports sufentanil or who proposes to engage in sufentanil's manufacture, distribution, importation, exportation, or research shall obtain a registration to conduct that activity by (date of publication), pursuant to Part 1301 of Title 21 of the Code of Federal Regulations.
2. **Security.** Sufentanil must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a)(c)(d), 1301.73, 1301.74, 1301.75(b)(c) and 1301.76 of Title 21 of the Code of Federal Regulations.
3. **Labeling and packaging.** All labels on commercial containers of, and all labeling of, sufentanil which is packaged after (date of publication) shall comply with the requirements of §§ 1302.03-1302.05 and 1302.07-1302.08 of Title 21 of the Code of Federal Regulations.
4. **Quotas.** Quotas for sufentanil are established pursuant to Part 1303 of Title 21 of the Code of Federal Regulations.
5. **Inventory.** Registrants possessing sufentanil are required to take inventories pursuant to § 1304.04 and §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations.
6. **Records.** All registrants must keep records pursuant to § 1304.04 and §§ 1304.21-1304.29 of Title 21 of the Code of Federal Regulations.

7. **Reports.** All registrants are required to file reports pursuant to §§ 1304.31-1304.41 of Title 21 of the Code of Federal Regulations.

8. **Order Forms.** Each distribution of sufentanil requires the use of an order form pursuant to Part 1305 of Title 21 of the Code of Federal Regulations.

9. **Prescriptions.** As sufentanil has been approved by the Food and Drug Administration for use in medical treatment, the drug may be dispensed by prescription. Prescriptions for sufentanil are to be issued pursuant to §§ 1306.01-1306.07 and §§ 1306.11-1306.15.

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

11. **Criminal Liability.** Any activity with sufentanil not authorized by or in violation of the Controlled Substances Act or the Controlled Substances Import and Export Act continues to be unlawful. The applicable penalties before (date of publication) shall be those of a Schedule I narcotic controlled substance. On May 25, 1984, sufentanil for the purposes of criminal liability shall be treated as a Schedule II narcotic controlled substance. The penalties of Schedule I or II narcotic controlled substances are the same. The only effect of the transfer may be for pleading purposes.

12. **Other.** In all other respects, this order is effective on May 25, 1984.

Pursuant to Title 5, United States Code, Section 605(b), the Administrator certifies that the rescheduling of sufentanil, as ordered herein, 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). Most of the regulatory requirements imposed on Schedule II substances are the same as those imposed on Schedule I substances. Additionally, substances in Schedule II may be used in medical treatment in the United States.

In accordance with the provisions of section 201(a) of the CSA (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.

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 the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR Part 0.100), the Administrator hereby orders that Part 1308, Title 21, Code of Federal Regulations (CFR) be amended as follows:

PART 1308—[AMENDED]

(1) By removing sufentanil as item (44) of § 1308.11(b) and renumbering items (45) tilidine and (46) tramperidine as items (44) and (45), respectively; and

(2) By amending paragraph (c) of § 1308.12 Title 21, Code of Federal Regulations (CFR), to include sufentanil therein as item (23), to read as follows:

§ 1308.12 Schedule II

* * * * *
 (c) * * *
 (23) Sufentanil.....9740
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Dated: May 18, 1984.
 Francis M. Mullen, Jr.,
 Administrator, Drug Enforcement Administration.

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DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 390

Administrative Offset of Claims; Correction

AGENCY: Bureau of the Public Debt, Fiscal Service, Treasury.
ACTION: Final rule; correction.

SUMMARY: This document corrects a drafting error and a typographical error contained in final regulations

implementing the administrative offset provisions of 31 U.S.C. 3716 which were published in 49 FR 6368 on February 21, 1984.

FOR FURTHER INFORMATION CONTACT: Mary Lou Dasburg, Attorney-Advisor, Bureau of the Public Debt, Office of the Chief Counsel, Divisions Office (202) 447-9859.

Accordingly, the Bureau of the Public Debt is correcting the following:

1. In the middle column on page 6369, delete the second paragraph under heading "List of Subjects in 31 CFR Part 390" and substitute the following language: "Accordingly, Part 390 is added to subchapter B of 31 CFR, Chapter II, to read as follows:"

2. In the middle column on page 6369, the fourth bold heading, "Part 90-Collection by Administrative Offset" should read "Part 390—Collection by Administrative Offset."

Dated: May 18, 1984.
 William M. Gregg,
 Commissioner of the Public Debt.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Ch. 1

[CGD 83-008]

Guide Clearances for Bridges Across Navigable Waters of the United States

AGENCY: Coast Guard, DOT.
ACTION: Adoption of Guide Clearances.

SUMMARY: The Coast Guard published a Notice of Proposed Adoption of Guide Clearances for Bridges across Navigable Waters of the United States in the March 28, 1983 Federal Register. A Supplemental Notice of Proposed

Adoption of Guide Clearances was published in the November 25, 1983 Federal Register. As a result of the comments received, a small number of minor changes have been made. Three new listings, previously overlooked, have been made. These are found as items 102, 103 and 104.

EFFECTIVE DATE: This adoption of Guide Clearances becomes effective May 25, 1984.

FOR FURTHER INFORMATION CONTACT: Mr. A. T. Meschter, 202-426-0342.

SUPPLEMENTARY INFORMATION: Guide Clearances are defined as the navigational clearances established by the Coast Guard for a particular navigable water of the United States which will ordinarily receive favorable consideration under the bridge permitting process (33 CFR Chapter 1, Subchapter J) as providing for the reasonable needs of navigation. The program of establishing Guide Clearances was initiated by the Corps of Engineers and later transferred to the Coast Guard. Under the Corps, Guide Clearances were called "Standard Clearances;" but the Coast Guard has since adopted the name "Guide Clearances" as more descriptive of the fact that these clearances are advisory, rather than mandatory. They are not intended to be regulatory in nature or to form a legal basis for approving or denying a bridge permit application. Under the circumstances of a particular case, greater or lesser clearances for a proposed bridge may be required or approved as meeting the reasonable needs of navigation for that particular location. For example, the particular character of the waterway and topography at the proposed location may justify a departure from the clearances specified for the waterway in the list of Guide Clearances.

Guide Clearances adopted or reaffirmed:

Waterway	Bridge type	Horizontal clearance	Vertical clearance	Reference plane
1. Fore River, ME: Mouth to head of Navigation	Fixed	200 ft.	135 ft.	MHW.
	Vertical Lift	200 ft.	135 ft (open) 20 ft (closed)	MHW.
2. Penobscot River, ME: Mouth to Bangor	Swing or bascule	200 ft.	20 ft (closed)	
	Fixed	450 ft.	135 ft.	MHW.
	Draw railroad	150 ft.	10 ft.	MHW.
	Draw highway	150 ft.	20 ft.	MHW.
3. Kennebec River, ME: Mouth to Augusta	Vertical Lift	150 ft.	135 (open)	MHW.
	Fixed	100 ft.	40 ft.	MHW.
4. Connecticut River, CT, MA above Hartford	Vertical Lift	100 ft.	40 ft (open) 15 ft (closed)	MHW.
	Swing or bascule	100 ft.	15 ft (closed)	
			20 ft (closed)	Above river level 16 ft.
5. Hudson River, NY: George Washington Bridge to northern limits of Irvington. Irvington to northern limits of Newburg. Newburg to Castleton. Castleton to Albany. Albany to US Dam Troy.	Fixed	1,500 ft.	100 ft.	MHW 8 ft stage Albany gage.
	Fixed	1,500 ft.	155 ft.	Do.
	Fixed	700 ft.	123 ft.	Do.
	Fixed	700 ft.	135 ft.	Do.
	Fixed	500 ft.	135 ft.	Do.
Vert. Lift	300 ft.	135 ft (open) 40 ft (closed)	Do.	