DEPARTMENT OF JUSTICE
Drug Enforcement Administration

[21 CFR Part 1308]

SCHEDULES OF CONTROLLED SUBSTANCES
Proposed Removal of Naltrexone From Control

Based upon the investigations of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to section 201(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(b)), the Administrator of the Drug Enforcement Administration finds that naltrexone has a currently accepted medical use in treatment of the United States and does not have sufficient potential for abuse or abuse liability to justify its continued control in any schedule under the Act. Naltrexone is presently controlled under Schedule II of the Act (§ 1308.12(b) of Title 21 of the Code of Federal Regulations) as a derivative of opium.

Therefore, under the authority vested in the Attorney General by section 201(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Administrator, Drug Enforcement Administration by § 301.600 of Title 20 of the Code of Federal Regulations, the Administrator hereby proposes that § 1308.12 (b) (1) of Title 21 of the Code of Federal Regulations be amended as follows:

§ 1308.12 Schedule II.

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding naltrexone and its salts, and excluding naltrexone and its salts, but including the following:

1. Raw opium
2. Opium extract
3. Opium fluid extract
4. Furred opium
5. Emulsi-faced opium
6. Tincture of opium
7. Apermorphine
8. Morphine
9. Ethylmorphine
10. Morphine hydrochloride
11. Hydrocodeine
12. Hydromorphone
13. Heroin
14. Mephenoxine
15. Orcodine
16. Orizocine
17. Thebaine

All interested persons are invited to submit their comments or objections in writing regarding this proposal. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Hearing Clerk, Office of Administrative Law Judge, Drug Enforcement Administration, Room 1130, 1405 Eye Street NW, Washington, D.C. 20537, and must be received no later than January 8, 1975.

In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be adopted and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail that a hearing will be held as soon as the matter may be heard, at the Drug Enforcement Administration, 1405 Eye Street NW, Washington, D.C. 20537. If objections submitted do not present such reasonable grounds, the party will be so advised by registered mail.

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


JOHN R. BARTLES, Jr.,
Administrator,
Drug Enforcement Administration.

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DEPARTMENT OF THE INTERIOR
Bureau of Mines

SALES OF HELIUM BY AND RENTAL OF CONTAINERS FROM BUREAU OF MINES

Fee Schedules

This revision is proposed pursuant to the Helium Act, approved September 13, 1960 (74 Stat. 918; 50 U.S.C. 167). The Department of the Interior proposes to amend Chapter VI, Subchapter A, Part 601 of Title 30, Code of Federal Regulations, entitled "Sales of Helium by and rental of containers from Bureau of Mines," by replacing the now existing schedule of prices and charges which became effective November 18, 1961. The proposed schedule of charges and prices are to be effective January 1, 1975.

This will be the first increase in 13 years and the need for new prices and charges is justified by the lapse of time alone. Some of the 1961 charges were either understated or were charged that had been in existence prior to the November 1961 schedule and were continued without updating. Another factor is that some charges include costs of labor and material, while others are predominantly labor costs. With regard to increases in the costs of materials, since 1961 the Wholesale Price Index, which is a general indicator of increased materials cost, has increased 44 percent. Wages have increased 88 percent. The overall increase for the proposed changes is 87 percent over the November 18, 1961, schedule of prices and charges.

The increased cylinder rates and all filling charges account for 83 percent of the total increase on the schedule. These are necessary because of the additional work necessary in quality control and the special attention needed in filling operations.

Some increases in service charges are based on value rather than on costs. This is true of the increase for the rental of cylinders. The price of 25 cents per month per cylinder has been in existence since the 1950's. The price under General Services Administration contracts for the lease of cylinders from industrial gas distributors is generally about $1.00 per month, with the first 2 months free. However, there are no commercial distributors that lease cylinders on a long-term basis as the Bureau does; therefore, there is no exactly comparable market value for cylinder rental. A good measure of the value of cylinders can be taken from the current market value for the purchase of new cylinders and the cost to maintain cylinders that are leased. A recent quote for new cylinders was $69 each, which is about double the 1961 cost. Delivery was not firm but estimated at 2 years. Using 30-year depreciation and 8-percent interest, a fixed cost of about $0.33 per month is obtained. Accounting records show that maintenance costs are about $0.70 per month, giving a total monthly cost of $0.70 per cylinder. This is the recommended charge. Although this is more than twice the present charge, it is realistic and in keeping with cost and value. It is also less than the rate charged under OSA contracts referred to above.

The attached schedule has been prepared in accordance with costs and value as provided in OMB Circular A-25. The attached schedule is dated August 26, 1971; the Secretary of the Interior's letter of June 8, 1966; and OMB