

proposed order or a modification of their terms.

JAMES A. TOBIN,
Acting Secretary.

[FR Doc. 78-25747 Filed 9-12-78; 8:45 am]

[4410-09]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed Placement of Pentazocine Into Schedule IV

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This is a notice of proposed rulemaking issued by the Administrator of the Drug Enforcement Administration (DEA) to place the drug pentazocine into schedule IV of the Controlled Substances Act (CSA). This action was initiated upon DEA's receipt of a letter from the Assistant Secretary for Health, Department of Health, Education, and Welfare (HEW), recommending that pentazocine be placed into schedule IV. The effect of this proposal would be to require that the manufacture, distribution, dispensing, importation and exportation of pentazocine be subject to controls for schedule IV substances.

DATE: Comments should be received on or before October 13, 1978.

ADDRESS: Send comments in triplicate to: Administrator, Drug Enforcement Administration, Department of Justice, 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, telephone 202-633-1366.

SUPPLEMENTARY INFORMATION: On February 2, 1978, the Administrator sent information concerning the abuse of the drug pentazocine and a recommendation to control the drug in schedule IV of the CSA to the Assistant Secretary for Health, HEW. The Administrator requested of the Assistant Secretary a scientific and medical evaluation of the information concerning pentazocine, and a recommendation as to whether and in which schedule under the CSA the drug should be controlled. On August 30, 1978, the Assistant Secretary replied:

Mr. PETER B. BENSINGER,
Administrator, Drug Enforcement Administration, Washington, D.C.

DEAR MR. BENSINGER: The Drug Enforcement Administration requested on February 2, 1978, that the Department of Health, Education and Welfare evaluate a proposal to control pentazocine in Schedule IV of the Controlled Substances Act.

The Bureau of Drugs within the Food and Drug Administration has reviewed the relevant data on pentazocine pursuant to Section 201 of the CSA and recommends that pentazocine (including all drug products containing pentazocine and its salts) be controlled in schedule IV of the CSA. I concur with this scientific and medical evaluation. A summary of the basis for this recommendation is enclosed.

Please accept my thanks to you and your staff for your cooperation in gathering the necessary data for the inherently difficult task of evaluating the issue of pentazocine control.

Sincerely yours,

JULIUS B. RICHMOND, M.D.,
Assistant Secretary for Health and Surgeon General.

Enclosure

The Drug Enforcement Administration has conducted a review of pentazocine which has included the following:

1. Published scientific and medical literature from the United States and other nations regarding this drug;
2. Material submitted to the Drug Enforcement Administration by the Department of Health, Education, and Welfare in support of the Assistant Secretary's letter recommending control for pentazocine;
3. Materials on file with the Food and Drug Administration, and the Drug Enforcement Administration; and
4. The legislative history of the Controlled Substances Act.

Based upon the investigations and review 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 sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), the Administrator of the Drug Enforcement Administration finds that:

1. Based on information now available, pentazocine has a low potential for abuse relative to the drugs or other substances currently listed in schedule III.
2. Pentazocine has a currently accepted medical use in treatment in the United States.
3. Abuse of pentazocine may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Therefore, under the authority vested in him by the Act and regulations of the Department of Justice,

the Administrator of the Drug Enforcement Administration hereby proposes that § 1308.14(f) of title 21 of the Code of Federal Regulations (CFR) be amended to read:

§ 1308.14 Schedule IV

* * * * *

(f) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

* * * * *

(2) Pentazocine 9,700

* * * * *

All interested persons are invited to submit their comments or objections in writing regarding this proposal. These comments and objections should state with particularity the issues concerning which the person desires to be heard. All such submissions must be received on or before October 13, 1978.

In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be finalized and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail of the time and place that the hearing will be held. If any objections which are submitted do not present reasonable grounds, the party will be so advised by registered mail.

If no objections presenting grounds for a hearing on this 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 consideration to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Dated: September 7, 1978.

PETER B. BENSINGER,
Administrator, Drug Enforcement Administration.

[FR Doc. 78-25507 filed 9-11-78; 8:45 am]

[3810-70]

DEPARTMENT OF DEFENSE

Office of the Secretary

[32 CFR Part 47]

DETERMINATIONS OF ACTIVE DUTY AND DISCHARGE

Civilian or Contractual Personnel

AGENCY: Office of the Secretary of Defense.