proposed rules

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed Placement of Dextropropoxyphene in Schedule IV

On June 29, 1973, the Director of the Bureau of Narcotics and Dangerous Drugs (DNDD), predecessor agency to the Drug Enforcement Administration, requested of the Acting Commissioner of the Food and Drug Administration that a scientific and medical evaluation and recommendation that dextropropoxyphene be placed in Schedule IV of the Controlled Substances Act be made by the Secretary of Health, Education and Welfare and submitted to BNDD.

By a letter dated January 23, 1976, the Assistant Secretary for Health requested the Drug Enforcement Administration to compile and provide FDA with additional data concerning propoxyphene.

On March 2, 1976, DEA provided FDA with the additional data.

By a letter dated August 12, 1976, the Assistant Secretary for Health submitted the scientific and medical evaluation and recommendation requested by BNDD that propoxyphene be controlled in Schedule IV of the Controlled Substances Act. The Assistant Secretary's letter is set out as follows:

DEPARTMENT OF HEALTH,
EDUCATION AND WELFARE,
OFFICE OF THE SECRETARY,
Washington, D.C., August 12, 1976.

MR. PETER BENSINGER,
Administrator, Drug Enforcement Administration, 1405 "Eye" Street, NW., Washington, D.C.

DEAR MR. BENSINGER: The Bureau of Narcotics and Dangerous Drugs (BNDD) requested on June 29, 1973 that the Department of Health, Education and Welfare evaluate a proposal to control dextropropoxyphene in Schedule IV of the Controlled Substances Act (CSA).

The Food and Drug Administration has reviewed relevant data on dextropropoxyphene pursuant to Section 201 of the CSA and recommends that dextropropoxyphene (including all drug products containing dextropropoxyphene 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.

I want to thank you and members of your staff for your cooperation in gathering the necessary data for the inherently difficult task of evaluating the issue of dextropropoxyphene control.

Appropriate staff members of the FDA will be available to assist the Drug Enforcement Administration in evaluating aspects of this recommendation and will make available any relevant information which you may need during the administrative procedures for drug control at DEA.

Sincerely yours,

J. F. DICKSON,
(For Theodore Cooper, M.D.,
Assistant Secretary for Health).

Enclosure.

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

1. Published scientific and medical literature from the United States and other nations regarding this drug;
2. Information obtained from knowledgeable persons in the medical and scientific community;
3. Field surveys regarding propoxyphene conducted by the Drug Enforcement Administration;
4. Information obtained from the United States Public Health Service;
5. Information obtained from the National Institute for Drug Abuse poly-Drug Program;
6. Information obtained from poison control centers;
7. Selected investigatory files compiled for law enforcement purposes by the Drug Enforcement Administration;
8. Materials submitted to the Drug Enforcement Administration by the Department of Health, Education, and Welfare in support of the Assistant Secretary's August 12, 1976 letter requesting control for propoxyphene;
9. Materials on file with the Food and Drug Administration, and the Drug Enforcement Administration; and
10. 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 Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a) and 811(b)), the Administrator of the Drug Enforcement Administration finds that:

1. Based on information now available, dextropropoxyphene has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.
2. Dextropropoxyphene has a currently accepted medical use in treatment in the United States.
3. Abuse of dextropropoxyphene 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 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 of the Drug Enforcement Administration by regulations of the Department of Justice, the Administrator proposes that § 1308.14 of Title 21 of the Code of Federal Regulations (CFR) be amended to read:

§ 1308.14 *Schedule IV.*

* * * * *

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

(1) Dextropropoxyphene (alpha-+-4-dimethylamino - 1,2-diphenyl-3-methyl-2-propionoxybutane- - - - - - -

All interested persons are invited to submit their comments or objections in writing regarding this proposal. The 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 Administrator, Drug Enforcement Administration, Department of Justice, Room 1130, 1405 Eye Street, NW., Washington, D.C. 20537, Attention: DEA Federal Register Representative, and must be received no later than December 1, 1976.

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 that a hearing on these objections 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 a hearing on the proposal are received within the time limitations, and all interested parties waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may, after giving consideration to written comments, issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Dated: September 23, 1976.

PETER B. BENSINGER,
Administrator,
Drug Enforcement Administration.

[FR Doc.76-28473 Filed 9-28-76;8:45 am]