drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances, 1965.

Corticoine, 167

Conferences have been held between the Bureau and the USV Pharmaceutical Corp., the only firm intending to market clortalidene in the United States. The USV Pharmaceutical Corp. has fully cooperated with the Bureau. Upon the conditions set forth in a letter to the Bureau from counsel for USV Pharmaceu
tical Corp., dated April 20, 1973, the manufacturer has consented to the placement of clortalidene in schedule III to ensure that it does not become subject to abuse in the future.

All other interested persons are in
ted to submit their comments or objec
tions in writing regarding this proposal. These comments or objections should state with particularity the issues con
cerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Hearing Clerk, Office of Chief Counsel, Bureau of Narcotics and Dangerous Drugs, Department of Justice, room 611, 1405 Eye Street NW, Washington, D.C. 20537, and must be received no later than June 11, 1973.

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 308.45, the party will be notified by registered mail that a hearing on these objections will be held at 10 a.m. on June 11, 1973, in room 1210, 1405 Eye Street NW, Washing
ton, D.C. 20537. If objections submitted do not present such reasonable grounds, the party will be so advised by registered mail.


[FR Doc.79-9071 Filed 5-9-79; 8:45 am]

PROPOSED RULES

SCHEDULES OF CONTROLLED SUBSTANCES
Proposed Placement of Fenfluramine in Schedule IV
On February 15, 1973, the Acting As
tistant Secretary for Health, on behalf of the Secretary of Health, Education, and Welfare, made the following letter to the As
tistant Secretary for Health, on behalf of the Secretary of Health, Education, and Welfare, to the Acting Assistant Secretary for Health, on behalf of the Secretary of Health, Education, and Welfare, as follows:

The Director of the Bureau of Narcotics and Dangerous Drugs:

Upon receipt of this letter, the Bureau undertook a review of the following:

(1) Materials submitted to NBDP by the Depart
ment of Health, Education, and Welfare with the letter of February 19, 1973;

(2) Materials submitted to the Food and Drug Administration in connection with the new drug applications on these drugs;

(3) Published scientific and medi
cal literature, including the literature from other nations regarding these drugs;

(4) Selected investigatory files compiled for law enforcement purposes by the Bureau and other law enforcement agencies;

(5) The legislative history of the Controlled Substances Act.

The results of this review can be summarized as follows:

(1) Fenfluramine is chemically similar to and related to the other anorectic drugs being proposed for control, and to amphetamine, methamphetamine, and phenmetrazine, substances currently listed in schedule II.

(2) Fenfluramine has a pharmacologi

cal profile which is similar to the other

anorectic drugs being proposed for control, to amphetamine, methamphetamine, and phenmetrazine. Although certain aspects of the fenfluramine profile are unique, this general similarity suggests that all of these drugs may be reasonably scheduled for use for therapeu
tic or abuse purposes.

(3) Fenfluramine is covered by a new drug application filed and pending with the Food and Drug Administration for use in treatment of obesity. The FDA has informed the Bureau that approval of this new drug application is pending completion of certain administrative matters.

(4) Products containing benzphetamine, chlorphentermine, diethylpropion, phenmetrazine, or phentermine have been marketed in the United States for several years. In the last 6 months, certain of these products have been reported as the subject of thefts, diversion, illicit sales, and abuse. Quantitatively, this type of abuse does not appear to be a problem at the present time; qualita
tively, the data indicates a trend to substi
tute these products for amphetamines and methamphetamine preparations in abuse circles. This reinforces the belief that abuse of the pharmacologically simi
lar drugs will increase as the amphetami
nes and methamphetamines become less and less available.

(5) Fenfluramine has not been mar
keted in the United States but has been continuously marketed in various Euro
pean and other countries over the last 10 years. Evidence concerning possible abuse of fenfluramine in South Africa has recently been brought to the attention of the Bureau but has not yet been evaluated by the Bureau; the material has been referred to the Department of Health, Education, and Welfare for its evaluation as well.

(6) The House Report on the Con
trolled Substances Act discusses the prob
lem of determining the abuse potential of a drug which has not been marketed, by quoting from regulations promulgated

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
Washington, D.C. 20201


John E. Ingersoll,
Director, Bureau of Narcotics and Dangerous Drugs,
Department of Justice, 1405 Eye Street NW, Washington, D.C. 20537

Dear Mr. Ingersoll:

The Food and Drug Administration has reviewed a re
view of all drugs currently marketed or pro
posed for marketing in the United States for the treatment of obesity. The marketed drugs include three substances already controlled under schedule II of the Controlled Substances Act, amphetamine, methamphetamine, and phenmetrazine. The review also included drugs currently not controlled under any schedule, the marketed drugs, diethylpropion, benzphetamine, phentermine, and chlorphentermine, and the investigational substances, clortalidene, mavidol, and fenfluramine. New drug appli
}
The Director has concluded from this review of the current situation that control of all anorectic drugs is at this time to prevent their becoming widely abused. This scheduling would fulfill the congressional mandate to act before substantial problems have arisen.

Because of the chemical and pharmacological similarities, fenfluramine and the other anorectic drugs being proposed for control, the Bureau is proposing placement of fenfluramine in schedule IV. The Bureau will monitor the manufacture, distribution, and use of fenfluramine in the United States, paying special attention to indicators of diversion (such as shortages in accountability audits of distributors and dealers, thefts from handlers, and availability on the illicit market) and to other indicators which indicate that fenfluramine is actually being abused (such as excessive prescribing and dispensing, reports of adverse reactions and overdoses, and other medical experiences). The Bureau will also consider, if available, clinical and other research in abuse, dependence-producing, and dependence-sustaining characteristics of fenfluramine. If, after 18 months during which the drug is marketed, experience suggests that fenfluramine has not been subject to significant diversion or abuse, the Director will review the necessity and desirability of maintaining fenfluramine in schedule IV and will request from the Secretary of Health, Education, and Welfare a new scientific and medical evaluation, and his recommendation, as to whether fenfluramine should be so controlled or removed as a controlled substance. Any interested person may petition the Bureau to decontrol fenfluramine at any time.

Based upon the investigations and review of the Bureau of Narcotics and Dangerous Drugs and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and (b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a), (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information evaluated up to this time, fenfluramine has a low potential for abuse relative to the drugs or other substances currently listed in schedule III, based on information now available. Although chemically and/or pharmacologically this drug is related to the other drugs being proposed for control and to the stimulants now listed in Schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse in other countries is not substantial enough to warrant a finding that fenfluramine has a potential for abuse equal to the stimulants in Schedule II or to the seven drugs listed above. In addition, certain tests cited in the letter from the Department of Health, Education, and Welfare suggest a lower abuse potential for fenfluramine.

2. Fenfluramine will be placed under the temporary control of the Food and Drug Administration. "Treatment of obesity" means temporarily under the care or control of a licensed health practitioner for the treatment of obesity. The anorectic drugs include those substances already controlled under schedule II of the Controlled Substances Act, amphetamine, methamphetamine, and phentermine. The review also includes drugs currently not controlled under any schedule, the marketed drugs, diethylpropion, amphetamine, phanolamine, and chlorphenamide. The review also includes drugs currently not controlled under any schedule, the marketed drugs, diethylpropion, amphetamine, phenmetrazine, chlorpromazine, and chlorpromazine, and the investigational substance, chlorpromazine, clonazolam, and fenfluramine. New drug applications have been submitted to the Food and Drug Administration for the latter three drugs, and approval is pending.

Review of data reveals that these drugs produce approximately the same degree of therapeutic effects in man as currently scheduled anorectic drugs. Additional weight reduction in the obese. The review indicated that the drugs are not vulnerable in other ways to drug abuse as are other scheduled anorectic drugs.