the district engineer becomes aware of plans being developed by either private or public entities who might require permits in order to implement the plans, he will advise the potential applicant in writing of the statutory requirements and the provisions of this regulation. Similarly when the district engineer is aware of changes in corps regulatory jurisdiction he will issue appropriate public notices.

(e) Reports.—The report of a district engineer on an application for a permit requiring action by the division engineer or by the Chief of Engineers will be in a letter form with the application and all comments, reports, records and studies including the final environmental impact statement if prepared, as enclosures. The following items will be included or discussed in the report:

(1) Name of applicant.
(2) Location of proposed work.
(3) Character and purpose of proposed work.
(4) Other Federal, State, and local authorizations obtained or required and pending.
(5) Date of public notice and public meeting or public hearings, if held, and summary of objections offered with comments of the district engineer thereon. The comments should explain the objections and not merely refer to inclosed letters.
(6) Views of State and local authorities.

(7) Views of district engineer concerning probable effect of the proposed work on:

(i) Navigation, present and prospective.
(ii) Harbor lines, if established.
(iii) Flood heights and drift.
(iv) Beach erosion or accretion.
(v) Fish and wildlife.
(vi) Water quality.
(vii) Aesthetics.
(viii) Ecology.
(ix) Historic values.
(x) Recreation.
(xi) Economy.
(xii) Water supply.
(xiii) Public interest.
(8) Other pertinent remarks, including need for the proposed work and alternatives reasonably available.

(9) A brief summary of the environmental impact statement, when required.
(10) Conclusions.

(11) Recommendations including any proposed special conditions.

[FR Doc.73-9300 Filed 5-9-73; 8:45 am]

DEPARTMENT OF JUSTICE

Bureau of Narcotics and Dangerous Drugs

[21 CFR Part 308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed Placement of Diethylpropion in Schedule III

On February 15, 1973, the Acting Assistant Secretary for Health, on behalf of the Secretary of Health, Education, and Welfare, sent the following letter to the Director of the Bureau of Narcotics and Dangerous Drugs:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

OFFICE OF THE SECRETARY

Washington, D.C. 20201


John E. Trevor,

Director, Bureau of Narcotics and Dangerous Drugs, Department of Justice, Washington, D.C.

Dear Mr. Trevor:

The Food and Drug Administration has recently completed a review of all drugs currently marketed or proposed 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, methampetaMine and phentermine. The review also included drugs currently not controlled under any schedule, the marketed drugs, diethylpropion, benzphetamine, phendimetrazine, phentermine, and chlorphenetermine, and the investigational substances, mazindol, mazindol, 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 as the currently scheduled anorectics, as adequate in weight reduction in the obese. The review indicated that the drugs are also comparable in other ways to scheduled anorectics:

a. They are all closely related chemically, with the exception of mazindol.

b. Their pharmacological profiles are closely similar, except for certain aspects of the profile of fenfluramine.

c. Documentation of actual abuse or production of dependence in humans is irregular, but does exist for certain of the unscheduled anorectics. The skimpy documentation of abuse of these drugs appears due to the fortuitous nature of reports as currently obtained and to the past easy availability of cheaper and more potent stimulants, rather than to intrinsic lack of abuse potential.

d. We note the conclusions and recommendations of the WHO Expert Committee on Drug Dependence that these drugs either be subject to control or be analogous to similar drugs recommended for control.

e. Certain specialized testing of fenfluramine suggests that the abuse potential of fenfluramine is of a lower order of magnitude than that of the other drugs under consideration.

We, therefore, conclude that all the above-named drugs possess abuse potential and potential for producing drug dependence, and are so informing you as required under the provisions of section 201(t) of the Controlled Substances Act. As provided for by section 201(a), we further request that the Attorney General issue rules adding the above drugs to the schedules of the Controlled Substances Act, and recommend that the schedule for all drugs be fenfluramine be schedule III, fenfluramine appearing more appropriately controlled under the provisions of schedule IV.

We attach review material assembled by reviewing pharmacologists within the Food and Drug Administration for its possible utility to you, and as a basis for further dis-
the regulations issued under the Drug Abuse Control Amendments of 1965 (id. at p. 34):

The Director may determine that a substance has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:

(1) There is evidence that individuals are taking the drug or preparing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or

(2) there is significant diversion of a drug or drugs containing such a substance from legitimate drug channels.

(3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.

The House Report goes on to say (id. at p. 35):

In speaking of substantial potential [for abuse] the term "substantial" means more than a mere specula of isolated abuse, but less than a preponderance. Therefore, documentation that, say, several hundred thousand doses of a particular drug have been diverted would be substantial evidence of abuse despite the fact that ten of millions of doses are made and are legitimately used in the same time period.

The Director has concluded from this review of the current situation that control of all anorectic drugs is desirable at this time to insure that they will not become widely abused. The scheduling will fulfill the congressional mandate to act before substantial problems have arisen.

Based upon the investigations and re-
view of the Bureau of Narcotics and Dangerous Drugs and upon the scient-
ific and medical evaluation and recom-
men-dation 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 now available, diethypropion has a potential for abuse less than the drugs currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anorectic drugs being proposed for control and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of diethypropion is not substan-
tial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Diethypropion has a currently ac-
ccepted medical use in treatment in the United States.

3. Abuse of diethypropion may lead to high psychological dependence.

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 Director of the Bureau of Narcotics and Dangerous Drugs by § 169 of title 28 of the Code of Federal Regulations, the Director proposes that section 301.13 of title 21 of the Code of Federal Regulations be amended to read:

§ 301.13 Schedule III.

(1) Stimulants—Rules generally accepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, iso-
mers (whether optical, position, or geo-
metric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Baryum, barium compounds, mixtures, or prepara-tions in dosage unit form containing any stimulant substances in accordance with paragraph 1.2 of this section, and any other drug of the quan-
titative composition shown in that list.

(b) Diethypropion ———— 1610

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 Chief Counsel, Bureau of Nar-
cotics and Dangerous Drugs, Department of Justice, room 811, 1405 Eye Street NW., Washington, D.C. 20537, and must be re-

In the event that an interested party submits objections to the proposal which present reasonable grounds for this rule not be finalized and requests a hearing in accordance with 21 CFR 308.45, the party will be notified by registered mail that a hearing will be held at 10 a.m. on June 11, 1973, in room 1210, 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 hear-
ing or to participate in the hearing, the Director may cancel the hearing and, after giving consideration to written comments, issue its final order pursuant to 21 CFR 308.48 without a hearing.


JOHN F. HENNESSEY,
Director, Bureau of Narcotics and Dangerous Drugs.