3, 1905 (33 U.S.C. 417), unless daily supervision or other unusual expenses are involved. In such unusual cases, and after approval by the division engineer, the permittee will be required to bear the expense of inspections in accordance with the conditions of his permit; however, the permittee will not be required or permitted to pay the U.S. inspector either directly or through the district engineer. The inspector will be paid on regular payrolls or service vouchers. The district engineer will collect the cost from the permittee in accordance with the following:

(i) At the end of each month the amount chargeable for the cost of inspection pertaining to the permit will be collected from the permittee and will be taken up on the statement of accountability and deposited in a designated depository to the credit of the Treasurer of the United States, on account of reimbursement of the appropriation from which the expenses of the inspection were paid.

(ii) If the district engineer considers such a procedure necessary to insure the United States against loss through possible failure of the permittee to supply the necessary funds in accordance with subparagraph (q)(4)(i) of this section, he may require the permittee to keep on deposit with the district engineer at all times an amount equal to the estimated cost of inspection and supervision for the ensuing month, such deposit preferably being in the form of a certified check, payable to the order of Treasurer of the United States. Certified checks so deposited will be carried in a special deposit account (guaranty for inspection expenses) and upon completion of the work under the permit the funds will be returned to the permittee provided he has paid the actual cost of inspection.

(iii) On completion of work under a permit, and the payment of expenses by the permittee without protest, the account will be closed, and outstanding deposits returned to the permittee. If the account is protested by the permittee, it will be referred to the division engineer for approval before it is closed and before any deposits are returned to the permittee.

(5) If the permitted activity includes restoration of the waterway to its original condition, or if the issuing official has reason to consider that the permittee might be prevented from completing work which is necessary to protect the public interest in the waterway, he may require the permittee to post a bond of sufficient amount to indemnify the Government against any loss as a result of corrective action it might take.

(r) *Publicity.*—District engineer will establish and maintain a program to assure that potential applicants for permits are informed of the requirements of this regulation and of the steps required to obtain permits for activities in navigable waters or ocean waters. Whenever 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.

(s) *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 pertinent comments, records, and studies including the final environmental impact statement if prepared, as inclosures. 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.
(iv) 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

Feb. 15, 1973.

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

DEAR MR. INGERSOLL: 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, methamphetamine and phenmetrazine. The review also included drugs currently not controlled under any schedule, the marketed drugs, diethylpropion, benzphetamine, phendimetrazine, phentermine, and chlorphentermine, and the investigational substances, clortermine, 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 in man as currently scheduled anorectics, as adjuncts 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 by analogy are similar to 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 abovenamed drugs possess abuse potential and potential for producing drug dependence, and are so informing you as required under the provisions of section 201(f) 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 but 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-

cussion after your scientists have reviewed our recommendations and request.

Sincerely,

RICHARD L. SEGGEL,
Acting Assistant Secretary for Health.

Upon receipt of this letter, the Bureau undertook a review of the following: (1) Materials submitted to BNDD by the Department of Health, Education, and Welfare with the letter of February 15, 1973; (2) materials submitted to the Food and Drug Administration in connection with new drug applications on these drugs; (3) materials submitted spontaneously to the Bureau by the manufacturer of diethylpropion regarding the abuse potential of this drug; (4) published scientific and medical literature from the United States and other nations regarding these drugs; (5) selected investigatory files compiled for law enforcement purposes by the Bureau and another law enforcement agency; and (6) the legislative history of the Controlled Substances Act.

The results of this review can be summarized as follows:

(1) Diethylpropion 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) Diethylpropion has a pharmacological profile which is similar to the other anorectic drugs being proposed for control and to amphetamine, methamphetamine, and phenmetrazine. This general similarity suggests that all of these drugs may be reasonably substituted for each other for therapeutic or abuse purposes.

(3) Diethylpropion is covered by a new drug application approved by the Food and Drug Administration for use in treatment of obesity.

(4) Products containing benzphetamine, chlorphentermine, diethylpropion, phendimetrazine, 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 data does not suggest a widespread problem at the present time; qualitatively, the data indicates a trend to substitute these products for amphetamine and methamphetamine preparations in abuse circles. This reinforces the belief that abuse of the pharmacologically similar drugs will increase as the amphetamines and methamphetamine become less and less available.

(5) The legislative history of the Controlled Substances Act makes clear that the Bureau is to schedule drugs based upon their potential for abuse, and should not be required to wait until a number of lives have been destroyed or substantial problems have arisen before designating a drug as subject to controls. (Comprehensive Drug Abuse Prevention and Control Act of 1970, House Report 91–1444 (part 1), p. 35, Sept. 10, 1970). Discussing factors used to measure potential for abuse, the report quotes from 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 drugs containing 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 the drug or drugs containing such a substance from legitimate drug channels; or
>
> (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 scintilla of isolated abuse, but less than a preponderance. Therefore, documentation that, say, several hundred thousand dosage units of a drug have been diverted would be substantial evidence of abuse despite the fact that tens of millions of dosage units of that drug 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. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen.

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 now available, diethylpropion has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although chemically and pharmacologically this drug is closely related to the other anoretic 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 diethylpropion is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Diethylpropion has a currently accepted medical use in treatment in the United States.

3. Abuse of diethylpropion 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 § 0.100 of title 28 of the Code of Federal Regulations, the Director proposes that section 308.13 of title 21 of the Code of Federal Regulations be amended to read:

§ 308.13 Schedule III.

* * * * *

(b) *Stimulants.*—Unless specifically excepted 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, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under § 308.32, and any other 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	1405
(2) Diethylpropion	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 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 7, 1973.

In the event that an interested party submits objections to this 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 on these objections 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 hearing or to participate in the hearing, the Director may cancel the hearing and, after giving consideration to written comments, issue his final order pursuant to 21 CFR 308.48 without a hearing.

Dated May 3, 1973.

JOHN E. INGERSOLL,
Director, Bureau of Narcotics and Dangerous Drugs.

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