

as such free transportation is not used, the continued existence of Part 233 will constitute no more than harmless surplusage.

Since this rule imposes no burden upon any person but merely constitutes an amendment to the Board's regulations of an interpretative and technical nature, so as to render them consistent with the Postal Reorganization Act, the Board finds that notice and public procedure hereon are unnecessary and the amendment may become effective immediately.

In consideration of the foregoing, the Civil Aeronautics Board hereby amends and reissues Part 233 of its Economic Regulations (14 CFR Part 233), effective June 12, 1973, as follows:

Sec.
233.1 Postal employees to be carried free.
233.2 Issuance of credentials and authorization of travel by Postal Service.

AUTHORITY.—Sec. 204(a) and 405(j) of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 760; 49 U.S.C. 1324, 1375; sec. 2 of the Postal Reorganization Act, 84 Stat. 767; 39 U.S.C. 5007.

§ 233.1 Postal employees to be carried free.

Every air carrier transporting the mails shall carry, on any flight that it operates and without charge therefor, persons on duty in charge of the mails or traveling to or from such duty, upon the exhibition of their credentials.

§ 233.2 Issuance of credentials and authorization of travel by Postal Service.

With regard to free air travel by the persons described in § 233.1, the Postmaster General shall be responsible for: (a) The issuance of proper credentials for such persons and (b) the authorization of travel by such persons, subject to such rules and regulations as he may prescribe.

By the Civil Aeronautics Board,

[SEAL] EDWIN Z. HOLLAND,
Secretary.

[FR Doc.73-11978 Filed 6-14-73;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS

PART 135a—NEW ANIMAL DRUGS FOR OPHTHALMIC AND TOPICAL USE

Chloramphenicol Ophthalmic Ointment, Veterinary

The Commissioner of Food and Drugs has evaluated a new animal drug application (65-158V) filed by EVSCO Pharmaceutical Corp., 3345 Royal Avenue, Oceanside, N.Y. 11572, proposing the safe and effective use of chloramphenicol ophthalmic ointment, veterinary, for the treatment of cats and dogs. The application is approved.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i)) and under authority delegated to the Commissioner (21 CFR 2.120), part

135a is amended in § 135a.29 by revising paragraphs (b) and (c) as follows:

§ 135a.29 Chloramphenicol ophthalmic ointment, veterinary.

(b) *Sponsor.*—See code No. 049 for use in accordance with paragraph (c) (1) (i) and code No. 053 for use in accordance with paragraph (c) (1) (ii) in § 135.501.

(c) *Conditions of use.*—(1) It is used in dogs and cats for the treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol as follows:

(i) It is applied every 3 hours around the clock for 48 hours after which night installations may be omitted. Treatment should be continued for 2 days after the eye appears normal.

(ii) It is applied to affected eye four to six times daily for the first 72 hours depending upon the severity of the condition. A small amount of ointment should be placed in the lower conjunctival sac. Continue treatment for 48 hours after eye appears normal.

(2) Therapy for cats should not exceed 7 days. Prolonged use in cats may produce blood dyscrasias. If improvement is not noted in a few days a change of therapy should be considered. When infection is suspected as the cause of a disease process especially in purulent or catarrhal conjunctivitis, attempts should be made to determine through susceptibility testing, which antibiotics will be effective prior to applying ophthalmic preparations. This chloramphenicol product must not be used in animals producing meat, eggs, or milk. The length of time that residues persist in milk or tissues has not been determined.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date.—This order shall be effective on June 15, 1973.

(Sec. 512(i), 82 Stat. 347; 21 U.S.C. 360b(i).)

Dated June 8, 1973.

C. D. VAN HOUWELING,
Director,
Bureau of Veterinary Medicine.

[FR Doc.73-11927 Filed 6-14-73;8:45 am]

CHAPTER II—BUREAU OF NARCOTICS AND DANGEROUS DRUGS, DEPARTMENT OF JUSTICE

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

Placement of Benzphetamine, Chlorphentermine, Clortermine, Diethylpropion, Mazindol, Phendimetrazine, and Phentermine in Schedule III, and Placement of Fenfluramine in Schedule IV

Notices were published in the FEDERAL REGISTER on May 9 and 10, 1973, proposing placement of benzphetamine (38 FR 19119), chlorphentermine (38 FR 12120), clortermine (38 FR 12121), diethylpropion (38 FR 12230), mazindol (38 FR 12124), phendimetrazine (38 FR 12126), and phentermine (38 FR 12127) in schedule III of the Controlled Substances Act, and fenfluramine (38 FR

12123) in schedule IV of the Controlled Substances Act. All interested persons were given until June 7, 1973, to file objections, comments, or requests for a hearing. A notice was published in the FEDERAL REGISTER on May 31, 1973, extending the time for filing to June 11, 1973 (38 FR 14286).

No objections nor requests presenting reasonable grounds for a hearing regarding the proposed orders on benzphetamine, chlorphentermine, clortermine, mazindol, and phendimetrazine were received. An objection and request for a hearing regarding the proposed orders on phentermine and fenfluramine was filed on May 21, 1973, and supplemented on June 11, 1973, by Pennwalt Corp. Details of these filings are discussed under the headings "Fenfluramine" and "Phentermine" below. An objection and request for a hearing regarding the proposed order on diethylpropion was filed on June 11, 1973, by Merrell National Laboratories, a division of Richardson Merrell, Inc. Details on this filing are discussed under the heading "Diethylpropion" below.

A comment was filed on May 23, 1973, by Lexington Chemical Co., Inc., Waltham, Mass., requesting that adequate time be provided between the publication of a final order and the effective date of such an order to provide industry sufficient opportunity to adjust to the new controls. The Bureau has considered this suggestion and believes that the effective dates set in this order comply with the spirit of the comment.

BENZPHETAMINE

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 section 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, benzphetamine 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 anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of benzphetamine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

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

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

The Director has concluded from his review of the current situation that control of all anorectic drugs, including benzphetamine, 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. The Upjohn Co., the only manufacturer of benzphetamine in bulk or dosage form in the United States, has fully cooperated with the Bureau and has consented to the placement of benzphetamine in schedule III to insure that it does not become subject to abuse in the future.

CHLORPHENTERMINE

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, chlorphentermine 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 anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of chlorphentermine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

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

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

The Director has concluded from his review of the current situation that control of all anorectic drugs, including chlorphentermine, 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.

CLORTERMINE

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, clortermine 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 anorectic drugs now being controlled and to the stimulants now listed in schedule II present data regarding these properties is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Clortermine will, upon the approval of new drug application by the FDA, have a currently accepted medical use in treatment in the United States.

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

The Director has concluded from his review of the current situation that control of all anorectic drugs, including clortermine, 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. The USV Pharmaceutical Corp., the only firm intending to market clortermine in the United States, has fully cooperated with the Bureau. Upon the conditions set forth in a letter to the Bureau from counsel for USV Pharmaceutical Corp. dated April 20, 1973, the manufacturer has consented to the placement of clortermine in schedule III to insure that it does not become subject to abuse in the future.

DIETHYLPROPION

The Bureau proposed placement of diethylpropion in schedule III, because it is one of the anorectics, control of which is desirable at this time (38 FR 12127).

Merrell National Laboratories, a division of Richardson Merrell, Inc., the only manufacturer of diethylpropion in the United States, filed comments, objections, and a request for a hearing regarding diethylpropion on June 11, 1973. In light of these objections and request for a hearing, the Director will not issue a final order controlling diethylpropion at this time.

FENFLURAMINE

The Pennwalt Corp., a manufacturer of a phentermine product called "Tonamin", filed comments, objections, and a request for a hearing regarding phentermine and fenfluramine on May 21, 1973. The comments of Pennwalt Corp. include the following paragraphs:

Pennwalt Corp. has no objection to the scheduling of "Tonamin" in schedule III, provided that the same scientific and legal principles which would lead to this scheduling of "Tonamin" are also applied to any other relevant product. Our objection, specifically, is that on the basis of information available to Pennwalt Corp. and to the field generally, there would appear to be more basis, or at least an equal basis, for placing fenfluramine in an equal or more restrictive schedule than "Tonamin".

It is Pennwalt's position that the Department of Health, Education, and Welfare erred in recommending to the BNDD that the products listed above, except for fenfluramine, be placed in schedule III, and that fenfluramine be placed in schedule IV. The basis for Pennwalt's position is twofold:

1. To the best of Pennwalt's knowledge, information and belief, the record of "Tonamin" with respect to abuse or any adverse consequences hardly rises to the de minimis level. There is no study, to our knowledge, by any reputable physician or institution which suggests that the risks, if any, in marketing "Tonamin" rise to the level of risk apparently already established for the use of fenfluramine.

2. The evidence with respect to the use of fenfluramine in Scotland, South Africa, and Jamaica, suggests to the physicians reporting their studies the risk of serious abuse, and serious withdrawal symptoms following the use of fenfluramine in controlled studies.

[Descriptions of five exhibits submitted by Pennwalt omitted.]

Pennwalt is aware that the Bureau of Narcotics and Dangerous Drugs, and presumably the Department of Health, Education, and Welfare, were aware of possible abuse in South Africa, as stated at page 12123 of the FEDERAL REGISTER, volume 38, No. 89, but Pennwalt believes that the material transmitted herewith demonstrates the basis upon which evaluation of fenfluramine should be made, when compared to the other products noted above.

In summary, fenfluramine appears to be the only product as to which there is serious adverse medical literature of record, and Pennwalt therefore believes that, as noted above, the scheduling of fenfluramine should be at no more permissive schedule than provided for the other relevant products.

On June 1, 1973, the Bureau notified Pennwalt Corp. that no objection had been raised regarding the control of fenfluramine, but only to the propriety of its placement in schedule IV. The Bureau interpreted this objection as a proposal to control fenfluramine in schedule III or, if fenfluramine is controlled in schedule IV as proposed, a petition to transfer fenfluramine from schedule IV to schedule III. Pennwalt Corp. was informed that, unless the company requested otherwise, the Bureau would consider the comments as a petition to place fenfluramine in schedule III and not as an objection to the current proposal to place fenfluramine in schedule IV. (A hearing on the proper schedule for fenfluramine would therefore be held only after receipt of the report of the Secretary of Health, Education, and Welfare, which has been now requested.) Pennwalt Corp. has not requested otherwise and no other objections have been received regarding the fenfluramine proposal.

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. Although chemically and/or pharmacologically this drug is related to the other anorectic drugs now being controlled 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 other anorectic drugs now being controlled. 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, upon the approval of a new drug application by the FDA, have a currently accepted medical use in treatment in the United States.

3. Abuse of fenfluramine may lead to limited physical dependence relative to the drugs or other substances in schedule III.

In making these findings, the Director is aware that material filed by the Pennwalt Corp., material previously referred to the Department of Health, Education, and Welfare for evaluation concerning possible abuse of fenfluramine in South Africa (see 38 FR 12123, May 9, 1973), and other evidence which may become available might necessitate findings regarding the abuse potential and dependence liability of fenfluramine justifying placement of the substance in schedule III. Therefore, the findings made in this order should not be construed as precluding new findings regarding fenfluramine in the near future in light of such evidence.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including fenfluramine, is at this time to prevent their becoming widely abused. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. The A. H. Robins Co., the only firm intending to market fenfluramine in the United States, has fully cooperated with the Bureau and has consented to the placement of fenfluramine in schedule IV to insure that it does not become subject to abuse in the future.

MAZINDOL

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) and (b)), the Director of the Bureau of Narcotics and Dangerous Drugs finds that:

1. Based on information now available, mazindol has a potential for abuse less than the drugs or other substances currently listed in schedule II. Although pharmacologically this drug is closely related to the other anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding these properties is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

2. Mazindol will, upon the approval of a new drug application by the Food and Drug Administration, have a currently accepted medical use in treatment in the United States.

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

The Director has concluded from his review of the current situation that control of all anorectic drugs, including mazindol, 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. Sandoz-Wander, Inc., the only firm intending to

market mazindol in the United States, has fully cooperated with the Bureau and has consented to the placement of mazindol in schedule III to insure that it does not become subject to abuse in the future.

PHENDIMETRAZINE

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, phendimetrazine 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 anorectic drugs now being controlled and to the stimulants now listed in schedule II, present data regarding excessive usage, diversion, illicit sales, and abuse of phendimetrazine is not substantial enough to warrant a finding that it has a potential for abuse equal to the stimulants in schedule II.

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

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

The Director has concluded from his review of the current situation that control of all anorectic drugs, including phendimetrazine, 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. The Ayerst Laboratories Division of the American Home Products Corp., the largest manufacturer of phendimetrazine in the United States and the only firm with a new drug application for phendimetrazine approved by the Food and Drug Administration, has fully cooperated with the Bureau and has consented to the placement of phendimetrazine in schedule III to insure that it does not become subject to abuse in the future.

PHENTERMINE

The Bureau proposed placement of phentermine in schedule III, because it is one of the anorectics control of which is desirable at this time (38 FR 12127).

The Dorsey Laboratories, Division of Sandoz-Warner, Inc., one of the two manufacturers of phentermine in the United States, has fully cooperated with the Bureau and has consented to the placement of phentermine in schedule III to insure that it does not become subject to abuse in the future.

Pennwalt Corp., the other manufacturer of phentermine in the United States, filed comments, objections, and a request for a hearing regarding phentermine and fenfluramine on May 21, 1973. The major portion of these com-

ments were set forth above under the heading "Fenfluramine." On June 11, 1973, Pennwalt Corp. supplemented its filing regarding its objections on phentermine. In light of these objections and request for a hearing, the Director will not issue a final order controlling phentermine at this time:

CONCLUSION

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 orders that:

1. Paragraph (b) of § 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) These 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) Benzphetamine 1230
- (3) Chlorphentermine 1645
- (4) Clortermine 1647
- (5) Mazindol 1605
- (6) Phendimetrazine 1620

2. Section 308.14 of title 21 of the Code of Federal Regulations be amended by the addition of a new paragraph to read:

§ 308.14 Schedule IV.

(c) *Fenfluramine.*—Any material, compound, mixture, or preparation which contains any quantity of the following substances, 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:

- (1) Fenfluramine 1670

FUTURE ACTION REGARDING ANORECTICS

Because of the similarities among the substances controlled by this order, and between those substances and the stimulants currently listed in schedule II, the Director is controlling these substances at this time in order to prevent their becoming the subject of abuse as amphetamines become less available in the illicit

market through the operation of the Bureau's regulatory controls and criminal enforcement actions. The Director believes that evidence suggests these anorectics may be future targets of stimulant abusers.

The Bureau will monitor the manufacture, distribution, and use of benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine in the United States, paying special attention to indicators of diversion (such as shortages in accountability audits of distributors and dispensers, thefts from handlers, and availability on the illicit market) and to other indicators which indicate that any of these substances are 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 abusability, dependence-creating, and dependence-sustaining characteristics of any of these substances. If, after 18 months during which these drugs are marketed, experience suggests that any of them have not been subject to significant diversion or abuse, the Director will review the necessity and desirability of maintaining it in schedule III (or, in case of fenfluramine, 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 that substance should be so controlled or removed as a controlled substance.

Any interested person may petition the Bureau to decontrol any of these substances at any time. If any petition is received to decontrol any one of these substances, or if the Director, based upon the review mentioned above, requests the evaluation and recommendation of the Secretary of Health, Education, and Welfare on any of these substances, all of the remaining substances will also be reviewed and, where appropriate, evaluations and recommendations regarding them will also be requested of the Secretary.

EFFECTIVE DATES

The requirements imposed upon the anorectic substances controlled by this order shall become effective as follows:

1. *Registration.*—Unless currently registered to conduct that activity with schedule III (or, in the case of fenfluramine, schedule IV) nonnarcotic substances, or unless exempted from registration by law, or pursuant to §§ 301.24-301.28 or 311.24-311.28 of title 21 of the Code of Federal Regulations, any person who manufactures, distributes, dispenses, imports, or exports benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine, or who proposes to engage in the manufacture, distribution, dispensing, importation, or exportation of any of those substances, shall obtain a registration to conduct that activity on or before August 1, 1973.

2. *Security.*—Benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine must be

manufactured, distributed, and stored in accordance with §§ 301.71, 301.72(b), 301.73, 301.74, 301.75(b), and 301.76 of title 21 of the Code of Federal Regulations on or before September 1, 1973. In the event that this poses special hardships, the Bureau will entertain any justified requests for extensions of time.

3. *Labeling and packaging.*—All labels on commercial containers of, and all labeling of, clortermine, fenfluramine, and mazindol which are packaged after June 18, 1973, shall comply with the requirements of §§ 302.03-302.05 and 302.08 of title 21 of the Code of Federal Regulations. In accordance with § 302.06 (c) of title 21 of the Code of Federal Regulations, the Director finds that early compliance with these requirements is necessitated by the fact that if these drugs, which have never before been marketed in the United States, fail to bear the appropriate symbol, physicians, pharmacists, distributors, and other handlers may not be aware that these drugs are now controlled under the Controlled Substances Act, thereby endangering the public health and safety. As noted above, early control of these substances has been undertaken to prevent abuse before it begins; prompt and adequate notice of control is essential to carry out this purpose.

All labels on commercial containers of, and all labeling of benzphetamine, chlorphentermine, and phendimetrazine which are packaged after September 1, 1973, shall comply with the requirements of §§ 302.03-302.05 and 302.08 of title 21 of the Code of Federal Regulations. In accordance with § 302.06(c) of title 21 of the Code of Federal Regulations, the Director finds that early compliance with these requirements is necessitated, again, by the fact that early control of these substances has been undertaken to prevent abuse before it becomes widespread; prompt and adequate notice of control is essential to carry out this purpose and thereby protect the public health and safety. In addition, the Director believes it would be unfair and discriminatory to allow any greater period of time between the effective dates of labeling for the new anorectics and the effective dates for those anorectics already being marketed.

In the event these effective dates pose special hardships on any manufacturer, the Bureau will entertain any justified requests for an extension of time.

4. *Inventory.*—Every registrant required to keep records who possesses any quantity of benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine shall take an inventory of all stocks of those substances on hand on September 1, 1973.

5. *Record.*—All registrants required to keep records pursuant to part 304 of title 21 of the Code of Federal Regulations shall maintain such records on benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine commencing on the date on which the inventory of those substances is taken.

6. *Prescriptions.*—All prescriptions for products containing benzphetamine,

chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine shall comply with §§ 306.01-306.06 and 306.21-306.25 of title 21 of the Code of Federal Regulations no later than September 1, 1973. Any prescription for any of the foregoing products which was issued before March 1, 1973, or which has been refilled more than five times, may not be refilled after September 1, 1973.

7. *Importation and exportation.*—All importation and exportation of benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine on and after September 1, 1973, shall be in compliance with part 312 of title 21 of the Code of Federal Regulations.

8. *Criminal liability.*—Any activity with benzphetamine, chlorphentermine, clortermine, fenfluramine, mazindol, and phendimetrazine, not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after June 15, 1973, shall be unlawful, except that any person who is not now registered to handle these substances but who is entitled to registration under those acts may continue to conduct normal business or professional practice with those substances between the date on which this order is published and the date on which he obtains the proper registration.

9. *Other.*—In all other respects, this order is effective on June 15, 1973.

Dated June 12, 1973.

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

[FR Doc.73-11935 Filed 6-14-73;8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Approval of Plan Revisions

On October 28, 1972 (37 FR 23085), pursuant to section 110(c) of the Clean Air Act, the Administrator promulgated regulations for several State implementation plans to correct disapproved portions of plans submitted by the States. A regulation providing for the review of new sources and modifications was promulgated for the State of New Jersey (37 FR 23091). Section 110(a)(2) of the Clean Air Act and 40 CFR 51.18 require that State implementation plans contain legally enforceable procedures which shall enable the States to prevent construction of new sources and modification of existing sources if such construction or modification will result in a violation of applicable portions of the State's control strategy or will interfere with attainment or maintenance of a national ambient air quality standard. The State of New Jersey, on March 22, 1973, submitted amended chapters 9 (permits) and 13 (ambient quality standards) of the New Jersey Air Pollution