RULES AND REGULATIONS

6. Section 97.31 is amended by originating, amending, or canceling the following Radar SIAPs, effective August 15, 1973:

Amarillo, Tex.—Amarillo Air Terminal, Radar-A, Amtd. 1
Charleston, W.Va.—Kenova Arpt., Radar-A, Amtd. 7
Charleston, W.Va.—Kenova Arpt., Radar-A, Amtd. 2

7. Section 97.33 is amended by originating, amending, or canceling the following Radar SIAPs, effective August 15, 1973:

Charleston, W.Va.—Kenova Arpt., RNNAV Rw 14, Amtd. 1
Charleston, W.Va.—Kenova Arpt., RNNAV Rw 28, Amtd. 1
Emporia, Kan.—Emporia Municipal Arpt., GNPR Rw 18, Orig.
Gaston, N.C.—Gaston Municipal Arpt., GNPR Rw 3, Orig.
Long Beach, Calif.—Long Beach (Daugherty Field) Arpt., RNNAV Rw 28R, Orig.


JAMES M. VINES,
Chief,
Airports Programs Division.

Note: Incorporation by reference provisions in §§ 97.10 and 97.20 (35 FR 5610) approved by the Director of the Federal Register on May 12, 1969.

[FR Doc. 73-13656 Filed 7-5-73; 8:45 am]

Title 21—Food and Drugs

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

PART 308—SCHEDULES OF CONTROLLED SUBSTANCES

Diethylpropion and Penthermin

Temporary Placement in Schedule IV; Interim Regulations

Notices were published in the Federal Register on May 9 and 10, 1973, proposing placement of benzphetamine (33 FR 19119), chlorphenetermine (33 FR 12120), clortemethyl (33 FR 12121), dihydronortestosterone (33 FR 12230), mazindol (33 FR 12124), phenmetrazine (33 FR 12126), and phentermine (33 FR 12127) in Schedule III of the Controlled Substances Act, and fenfluramine (33 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 (33 FR 14288).
On June 15, 1973, a final order was issued placing benzphetamine, chlorphenmetramine, clorertamine, mazindol, and phendimetrazine in Schedule III of the Controlled Substances Act and fenfuramine in Schedule V of the Controlled Substances Act (38 F.R. 17179).

Objections and a request for a hearing were filed on the proposal to control diethylpropion by Merrell National Laboratories, a division of Richardson Merrell, Inc., the manufacturer of that substance. Objections and a request for a hearing were filed on the proposal to control phentermine by Pennwalt Corporation, a manufacturer of that substance. The Bureau is currently seeking acceptable dates for hearings on these objections.

Until such hearings can be completed, however, the Bureau believes that interim control of diethylpropion and phentermine is desirable. These two substances are reported to be among the most widely prescribed of the non-amphetamine anorectic drugs in the United States. The Bureau's concern that such drugs are likely targets for future abuse and that there is a need to control diethylpropion and phentermine because of the wide availability. In addition, in controlling benzphetamine, clorertamine, mazindol and phendimetrazine, the Bureau had indicated to manufacturers that their consenting to control would not be allowed to place them at a competitive disadvantage with other substances being proposed for Schedule III. In light of these considerations, the Director requested that Merrell National Laboratories and Pennwalt Corporation consent, respectively, to the placement of diethylpropion and phentermine in Schedule IV of the Controlled Substances Act in the interim before hearings can be held and a final order issued on the proposals to place each substance in Schedule III.

Merrell National Laboratories and Pennwalt Corporation have cooperated with the Director in this request in order to assure that the public's need for control of diethylpropion and phentermine during the next few weeks is minimized. Both manufacturers have stated, and the Bureau has agreed, that the consent does not constitute an admission to any facts or findings regarding the abuse potential or dependence liability of the two substances, nor a waiver of the right to contest any assertion of fact or law involved in the hearings on placement in Schedule III, nor a withdrawal of the requests for such hearings, nor does it alter the burden of proof of facts in such hearings. In the same manner this interim action in no way affects the Bureau's proposal that diethylpropion and phentermine be placed in Schedule III. For all parties this interim order represents the most expedient course of action necessary to protect public health and safety, to preserve the rights of the manufacturers of diethylpropion and phentermine, and to observe the legitimate interests of the manufacturers of the other anorectic drugs now controlled.

The Bureau connotes that the published proposals to place diethylpropion and phentermine in Schedule III comply with the procedures required by section 201 of the Controlled Substances Act and as such are subject to the administrative review process provided in Schedule IV, in this situation. The pertinent regulatory controls on Schedules III and IV are substantially identical. There being no objections to the placement of these substances under Schedule IV (other than those of the two manufacturers), it would appear unlikely that anyone would now object to their placement in Schedule IV, except possibly for manufacturers of other anorectic drugs in competition with diethylpropion and phentermine. The Bureau has consulted with these manufacturers and each agreed to this interim action. The USV Pharmaceutical Corporation so agreed on conditions which are acceptable to the Bureau and which will be set forth in a letter to be dated July 2, 1973 from counsel for the Corporation. Therefore, under these unusual circumstances the Director finds that section 201 has been complied with and no further proposal before the Bureau is needed to place diethylpropion and phentermine in Schedule IV at this time.

DIETHYLPROPION

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 low potential for abuse relative to the drugs or other substances currently listed in Schedule III.
2. Diethylpropion has a currently accepted medical use in treatment in the United States.
3. Abuse of phentermine may lead to limited psychological dependence relative to the drugs or other substances in Schedule III.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including phentermine, is desirable at this time to prevent their use and abuse. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. The Bureau, therefore, has 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. The Pennwalt Corporation, the other manufacturer 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. The Pennwalt Corporation, the other manufacturer of phentermine in the United States, has fully cooperated with the Bureau. The Bureau has 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. The Pennwalt Corporation, the other manufacturer of phentermine in the United States, has fully cooperated with the Bureau. The Bureau has 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.

The Director has concluded from his review of the current situation that control of all anorectic drugs, including diethylpropion, is desirable at this time to prevent their use and abuse. This scheduling will fulfill the congressional mandate to act before substantial problems have arisen. The Bureau, therefore, has 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. The Pennwalt Corporation, the other manufacturer of phentermine in the United States, has fully cooperated with the Bureau. The Bureau has 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.
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 § 308.14 of Title 21 of the U.S. Code of Federal Regulations be amended by the addition of a new paragraph to read:

§ 308.14 Schedule IV.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing the specific chemical substance, identity of the following substances having a stimulant effect on the central nervous system, including its salts; isomers (whether optical, positional, or geometric), and salts of such isomers wherever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Diethylpropion 1810
(2) Phentermine 1840

Future Action Regarding Anorectics

Because of the similarities among the substances controlled by this order, and between the substances and the stimulants currently listed in Schedules II and III, the Director is controlling these substances at this time in order to prevent their becoming the subject of abuse and amphetamine use in the illicit market through the operation of the Bureau's regulatory controls and criminal enforcement actions. The Director believes that the stimulants and the substances may also be subject to widespread abuse. The Bureau intends to proceed to hearings on the placement of diethylpropion and phentermine in Schedule III in the near future. The times and places of such hearings will be announced shortly.

The Bureau, over a longer period, will monitor the manufacture, distribution, and use in the United States of diethylpropion and phentermine, as well as those anorectic drugs controlled on June 13, 1973, with special attention to indicators of diversion (such as shortages in accountability audits of distributors and pharmacies, thefts from pharmacies, and availability on the illicit market). The Director will consider if available, clinical, and other research in abuse liability, dependance-producing, and dependence-sustaining capacities of any of the Bureau of Narcotics and Dangerous Drugs. 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 feasibility of maintaining them under control and will request from the Secretary of Health, Education, and Welfare a new scientific and medical evaluation of the need to maintain these substances on Schedule IV, 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 and, if appropriate, 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 IV 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, imports, exports, dispenses, possesses, or who proposes to engage in the manufacture, distribution, dispensing, importing, or exportation of either of those substances, shall, in order to conduct that activity on or before August 1, 1973.

2. Security. Diethylpropion and phentermine must be manufactured, distributed, and stored in accordance with §§ 301.71, 301.72(b), 301.73, 301.74, 301.75(b) and 310.76 of Title 21 of the Code of Federal Regulations on or before September 1, 1973, and in the event that this poses special hardship, the Bureau will entertain any justified request for extensions of time.

3. Labeling and packaging. All labels on commercial containers of, and all labeling of, diethylpropion and phentermine 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 § 302.08(a) of Title 21 of the Code of Federal Regulations, the Director finds that compliance with these requirements is necessitated 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.

Title 22—Foreign Relations
CHAPTER II—AGENCY FOR INTERNATIONAL DEVELOPMENT, DEPARTMENT OF STATE

PART 201—RULES AND PROCEDURES APPLICABLE TO COMMODITY TRANSACTIONS FINANCED BY AID.

Modification of Provisions Concerning Supplier's Certificate

The amendment (1) extends from June 30, 1973 to August 30, 1973, the time during which the AID Supplier's Certificate, designated as AID 282 (1-1-73), may be submitted, to allow more time for the new Supplier's Certificate to be distributed throughout the business community and permitting that distribution to permit the old Supplier's Certificate to continue in use. Amendment (2) deletes Appendix C from the regulation, because the certificate described by Appendix C is no longer required under the