Procedure Act (5 U.S.C. 553(b)). Therefore, the Commission hereby amends Title 16, Chapter II, Subchapter D, Part 1630, by adding a new Subpart D, as follows:

Subpart D—Interpretations and Policies

§ 1630.81 Policy on recall of noncomplying carpets and rugs.

(a) *Purpose.* The purpose of this section is to state the policy of the Commission concerning recall of carpets and rugs which are subject to and fail to comply with the Standard for the Surface Flammability of Carpets and Rugs (FF 1-70) (16 CFR Part 1630, Subpart A). In this policy statement, the Commission reaffirms that provisions of the Flammable Fabrics Act (FFA) authorize recall of any product which fails to comply with an applicable flammability standard issued under that Act. Additionally, this policy statement announces general principles which will be followed by the Commission in exercising the authority contained in the FFA to require recall of carpets and rugs from various levels of distribution, including carpets and rugs in the possession of the ultimate consumer.

(b) *Recall from distributors and retailers.* The Commission will exercise the authority contained in the FFA to order recall of carpets and rugs which fail to comply with the Standard for the Surface Flammability for Carpets and Rugs and which are in the possession of any distributor, retailer, or other person or firm in the chain of distribution, where the facts, including the number and pattern of test failures, indicate that such action is necessary and appropriate.

(c) *Recall from consumers.* (1) In cases involving carpets and rugs distributed in commerce by a domestic manufacturer, or imported into the United States, after July 11, 1978, the Commission will exercise the authority contained in the FFA to order recall of carpets and rugs which fail to comply with the Standard for the Surface Flammability of Carpets and Rugs and which are in the possession of ultimate purchasers, including installed carpet, where the facts, including the number and pattern of test failures, indicate that such action is necessary and appropriate.

(2) The Commission may exercise the authority of section 15 of the Consumer Product Safety Act (15 U.S.C. 2064) to order the repair, replacement, or repurchase of any carpets or rugs in the possession of ultimate purchasers, including installed carpet, if such carpets and rugs present a "substantial product hazard" as that term is used in the Consumer Product Safety Act in any case involving carpets or rugs which were distributed in commerce by a domestic manufacturer or imported into the United States, on or before July 11, 1978, or any time thereafter.

AUTHORITY: Sec. 5, 15 U.S.C. 1194; 67 Stat. 112, June 30, 1953; Sec. 5, 15 U.S.C. 45(b), 38 Stat. 719, Sept. 26, 1914; Sec. 15, 15 U.S.C. 2064, 86 Stat. 1221, Oct. 27, 1972.

Dated: January 2, 1979.

SADYE E. DUNN,
Secretary, Consumer Product Safety Commission.

[FR Doc. 79-824 Filed 1-9-79; 8:45 am]

[4410-09-M]

Title 21—Food and Drugs

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Placement of Pentazocine Into Schedule IV

AGENCY: Drug Enforcement Administration.

ACTION: Final rule.

SUMMARY: This rule requires that the manufacture, distribution, dispensing, importation and exportation of pentazocine and its salts be subject to the controls provided by the Controlled Substances Act and regulations of the Drug Enforcement Administration, for substances in Schedule IV.

This rule is issued as a result of the Drug Enforcement Administration's request that the Assistant Secretary for Health, Department of Health, Education and Welfare, provide DEA with a scientific and medical evaluation of pentazocine regarding its placement into Schedule IV of the Act, the Assistant Secretary's transmittal of the requested recommendation and evaluation, publication of a Notice of Proposed Rulemaking to place pentazocine into Schedule IV in the FEDERAL REGISTER (43 FR 40884, Sept. 13, 1978), and receipt and review by DEA of comments submitted in response to the published Notice.

DATE: Effective date of schedule IV control: February 9, 1979, except as otherwise provided in Supplementary Information section of this order.

FOR FURTHER INFORMATION CONTACT:

Howard McClain, Jr., Chief, Regulatory Control Division, Office of Compliance and Regulatory Affairs, Drug Enforcement Administration, telephone 202-633-1366.

SUPPLEMENTARY INFORMATION: A notice was published in the FEDERAL REGISTER on September 13, 1978 (43 FR 40884) proposing that the drug pentazocine, and its salts, be placed into Schedule IV of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801-966), and that Title 21, Code of Federal Regulations (CFR) Section 1308.14 [Schedule IV] be amended accordingly.

All interested persons were given until October 13, 1978, to submit their comments or objections in writing regarding this proposal.

In response to the notice, nine comments were received by DEA. Of these, five were in support of DEA's proposal to place pentazocine in Schedule IV; two, submitted by the South Carolina Bureau of Drug Control, and by the Assistant Director of Pharmacy for the Methodist Hospital, Memphis, Tennessee, advocated pentazocine for Schedule II; one, by Crouse Irving Memorial Hospital, Syracuse, New York, was informational and advisory; and one, by Sterling Drug Inc., manufacturer of Talwin brand of pentazocine, set forth comments, objections and two requests for hearings concerning Talwin Compound, which is pentazocine combined with aspirin, and butorphanol, a drug newly marketed as an analgesic and currently not a controlled substance.

All the comments thus submitted were reviewed and considered by the Drug Enforcement Administration, and especially noted are the comments, data and materials provided by the Rhode Island Department of Health, Crouse Irving Memorial Hospital, the State of Wisconsin Controlled Substances Board, and the South Carolina Bureau of Drug Control; these submissions were especially helpful in providing profiles of pentazocine abuse cases and a heightened perspective of patterns of pentazocine abuse potential. Although this information and data could well support more stringent controls for pentazocine than are established by this Order, it all is being retained by DEA for use as a basis for further control of pentazocine if, in the future, more stringent controls for the drug are warranted. As to the aforementioned letter filed with DEA by Sterling Drug Inc., it has been reviewed by the Administrator, who has determined that it fails to present reasonable grounds for the proposed rulemaking concerning pentazocine not to be finalized. Sterling Drug Inc. has been notified of this action by letter, dated December 22, 1978.

Additionally, South Carolina, in commenting on the DEA proposal, objected to that proposal and disputed the Schedule IV findings regarding po-

tential for abuse and dependence by the Administrator as set forth therein. South Carolina provided additional information which it asserted would support the findings necessary for placing pentazocine in Schedule II, and advocated that the Administrator issue a proposed rule to that effect.

As noted above, DEA is retaining the information submitted by South Carolina in this regard for possible future use, and has notified the South Carolina Bureau of Drug Control accordingly.

Finally, of historical note, on October 5, 1971, a petition was filed with the Bureau of Narcotics and Dangerous Drugs, predecessor agency to DEA, to place injectable liquid pentazocine into Schedule III of the Act. The petition was filed by Joseph L. Fink, III, then a law student, and six other persons. In respect of the petition, a notice was published in the FEDERAL REGISTER on November 10, 1971, which advised that their petition had been accepted for filing and BNDD would conduct a review thereof to determine if the requested rulemaking proceedings should be initiated.

In view of the August 30, 1978, recommendation and evaluation received from the Assistant Secretary for Health concerning pentazocine, and the instant order issued today in respect thereof listing pentazocine in Schedule IV, the October 5, 1971, petition is hereby denied pending receipt by the Administrator of additional information from petitioners or any other interested person or persons which justifies initiating proceedings to transfer the injectable liquid form of pentazocine from Schedule IV to Schedule III.

No further comments nor objections were received, nor were there any other requests for a hearing, and in view thereof, and based upon the investigations and review of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Assistant Secretary for Health in behalf of the Secretary of Health, Education, and Welfare, received pursuant to Sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), the Administrator of the Drug Enforcement Administration finds that:

1. Based on information now available, pentazocine has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.

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

3. Abuse of pentazocine may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

Therefore, under the authority vested in him by the Act and regulations of the Department of Justice, the Administrator of the Drug Enforcement Administration hereby orders that § 1308.14(f) of title 21 of the Code of Federal Regulations (CFR) be amended to read:

§ 1308.14 Schedule IV.

* * * * *

(f) *Other substances.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

* * * * *

(2) Pentazocine	9709

EFFECTIVE DATES

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports, pentazocine, or who proposes to engage in such activities, shall submit an application for registration to conduct such activities in accordance with Parts 1301 and 1311 of Title 21 of the Code of Federal Regulations on or before February 9, 1979.

2. *Security.* Pentazocine must be manufactured, distributed, and stored in accordance with §§ 1301.71, 1301.72(b)-(d), 1301.73, 1301.74(a)-(f), 1301.75(b)-(c), and 1301.76 of Title 21 of the Code of Federal Regulations on or before July 9, 1979. From now until the effective date of this provision, it is expected that manufacturers and distributors of pentazocine will initiate whatever preparations as may be necessary, including undertaking handling and engineering studies and constructions programs, in order to provide adequate security for pentazocine in accordance with DEA regulations so that substantial compliance with this provision can be met by (180 days after date of publication). In the event that this imposes special hardships, the Drug Enforcement Administration will entertain any justified requests for extensions of time.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of pentazocine packaged after July 9, 1979, shall comply with the requirements of § 1302.03-1302.05 and 1302.08 of Title 21 of the Code of Federal Regulations. In the event this effective date imposes special hardships on any manufacturer, as defined in Section 102(14) of the Controlled Substances Act (21 U.S.C. 802(14)), the Drug Enforcement Administration will entertain any justified requests for an extension of time.

4. *Inventory.* Every registrant required to keep records who possesses any quantity of pentazocine shall take an inventory prusuant to § 1304.11-1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of such substances on hand, February 9, 1979.

5. *Records.* All registrants required to keep records pursuant to § 1304.21-1304.27 of Title 21 of the Code of Federal Regulations shall maintain such records on pentazocine commencing on the date on which the inventory of such substances is required to be taken.

6. *Prescriptions.* All prescriptions for products containing pentazocine shall comply with §§ 1306.01-1306.06 and §§ 1306.21-1306.25 of Title 21 of the Code of Federal Regulations, beginning February 9, 1979. All prescriptions for products containing such substances issued before February 9, 1979, if authorized for refilling, shall as of that date be limited to five refills and shall not be refilled after August 8, 1979.

7. *Importation and exportation.* All importation and exportation of pentazocine shall, on or after February 9, 1979, be required to be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

8. *Criminal liability.* The Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to pentazocine not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after February 9, 1979, shall be unlawful, except that any person who is not now registered to handle this substance but who is entitled to registration under such Acts may continue to conduct normal business or professional practice with pentazocine under this authority between the date on which this Order is published and the date on which he obtains or is denied registration.

9. *Other.* In all other respects, this Order is effective February 9, 1979.

Dated: January 4, 1979.

PETER B. BENSINGER,
Administrator.

[FR Doc. 79-898 Filed 1-9-79; 8:45 am]

[4910-22-M]

Title 23—Highways

CHAPTER I—FEDERAL HIGHWAY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION