The summary is available for public examination at the office of the Hearing Clerk, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, Monday through Friday from 9 a.m. to 4 p.m., except on Federal legal holidays.

Therefore, under 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 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 520 is amended in § 520.260 by revising paragraph (b)(2) to include a sponsor for a 221 milligram capsule to read as follows:

§ 520.260 *n*-Butyl chloride capsules.

* * * * *

(b) * * *

(2) *Sponsors.* See No. 015563 in § 510.600(c) of this chapter for 221, 442, 884, or 1,768 milligram or 4.42 gram capsules; No. 012983 in 510.600(c) of this chapter for 884 or 1,768 milligram or 4.42 gram capsules; and No. 000069 in 510.600(c) of this chapter for 221 milligram capsules.

* * * * *

Effective date. This amendment shall be effective February 11, 1977.

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

Dated: February 3, 1977.

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

[FR Doc.77-4199 Filed 2-10-77;8:45 am]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Placement of Dextropropoxyphene in Schedule IV

On September 23, 1976, the Administrator of the Drug Enforcement Administration issued a notice of proposed rulemaking to amend § 1308.14 of Title 21 of the Code of Federal Regulations (CFR) to include dextropropoxyphene in Schedule IV of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq.). This notice was published in the FEDERAL REGISTER on September 29, 1976 (41 FR 42957) and provided an opportunity for all interested persons to submit comments, objections and requests for a hearing on the matter, no later than December 1, 1976.

The notice further provided that if objections submitted presented reasonable grounds for the proposed rule not to be finalized, and if a hearing were requested, such hearing would be held as soon as the matter could be heard before the Drug Enforcement Administration. The notice also stated that if all interested parties waived their opportunity to request or participate in a hearing, the Administrator could, without a hearing, issue his final order pursuant to 21 CFR 1308.48 after giving consideration to written comments submitted.

Ten letters setting forth comments or objections to the proposed rulemaking were received by the Drug Enforcement Administration. Four of the letters received favored the proposed rulemaking. Of the remaining letters, most were concerned with being given enough time to install new or to expand existing security measures for the drug should a final order be issued placing the drug in Schedule IV.

In consideration of these comments, the Administrator has provided in the order issued today that all registrants shall have six months from the date of this order within which to comply with the security provisions thereof, and in the event this imposes special hardships, the Drug Enforcement Administration will entertain any justifiable requests for extension of time.

Three letters expressed opposition to the proposed rulemaking, alleging lack of evidence sufficient to justify control.

In the notice of proposed rulemaking issued September 23, 1976 there was set forth a ten-point list detailing the review of dextropropoxyphene this Agency conducted. In addition, on August 13, 1976, in response to our request, we received from the Department of Health, Education and Welfare its separate review and its recommendation that dextropropoxyphene should be controlled in Schedule IV of the Act. The Administrator therefore concludes that, contrary to the objections submitted, there is compelling evidence to justify control of the drug as proposed.

In none of the comments which were received was there a request for a hearing. On this point it is noted that Eli Lilly and Company, the principal manufacturer of dextropropoxyphene, has voluntarily shared with the Drug Enforcement Administration and the Food and Drug Administration data developed in its continuing studies relating to dextropropoxyphene. In keeping with the Company's announced policy of concern respecting matters possibly affecting the public health, Lilly has not opposed the proposed listing of dextropropoxyphene in Schedule IV, and did not request a hearing on the proposal. The Administrator appreciates the cooperation given by Lilly and commends the Company for the corporate responsibility it has so clearly demonstrated.

Based upon the investigations and review of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Department 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 finds that:

1. Dextropropoxyphene has a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.

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

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

and, under the authority vested in the Administrator of the Drug Enforcement Administration, the Administrator hereby orders that § 1308.14 of Title 21 of the Code of Federal Regulations (CFR) be amended to read:

§ 1308.14 Schedule IV.

* * * * *

(e) *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:

(1) Dextropropoxyphene (Alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane)	8121

EFFECTIVE DATES

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports dextropropoxyphene, 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 March 14, 1977.

2. *Security.* Dextropropoxyphene 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 August 14, 1977. From now until the effective date of this provision, it is expected that manufacturers and distributors of dextropropoxyphene will initiate whatever preparations as may be necessary, including undertaking handling and engineering studies and construction programs, in order to provide adequate security for dextropropoxyphene in accordance with DEA regulations so that substantial compliance with this provision can be met by August 14, 1977. 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 dextropropoxyphene packaged after August 14, 1977, 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 dextropropoxyphene shall take an inventory pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations, of all stocks of such substances on hand, on March 14, 1977.

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 dextropropoxyphene commencing on the date on which the inventory of such substances is taken.

6. *Prescriptions.* All prescriptions for products containing dextropropoxyphene shall comply with §§ 1306.01–1306.06 and §§ 1306.21–1306.25 of Title 21 of the Code of Federal Regulations, beginning March 14, 1977. All prescriptions for products containing such substances issued before March 14, 1977, if authorized for refilling, shall as of that date be limited to five refills and shall not be refilled after September 14, 1977.

7. *Importation and exportation.* All importation and exportation of dextropropoxyphene shall, on or after March 14, 1977, be required to be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

8. *Criminal liability.* Pursuant to Title 21 of the Code of Federal Regulations, § 1308.49, the Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to dextropropoxyphene not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act, conducted after March 14, 1977 shall be unlawful, except that any person who is not now registered to handle these substances but who is entitled to registration under such Acts may continue to conduct normal business or professional practice with dextropropoxyphene 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 on March 14, 1977.

Dated: February 7, 1977.

PETER B. BENSINGER,
Administrator,
Drug Enforcement Administration.

[FR Doc.77-4407 Filed 2-10-77;8:45 am]

Title 31—Money and Finance: Treasury

CHAPTER II—FISCAL SERVICE, DEPARTMENT OF THE TREASURY

PART 223—SURETY COMPANIES DOING BUSINESS WITH THE UNITED STATES

Revision of Regulations Which Govern Surety Companies Doing Business With United States

AGENCY: Bureau of Government Financial Operations.

ACTION: Final Rule.

SUMMARY: The Department of the Treasury is amending its surety regulations at 31 CFR Part 223 in order to clarify and update the regulations in light of current practices; to remove the only technical requirements contained in Part 223; and to revise its schedule of fees to recover costs related to services performed for and special benefits conferred upon surety companies by the Department.

EFFECTIVE DATE: February 4, 1977.

FOR FURTHER INFORMATION CONTACT:

Mr. Guy Kelly, Insurance Company Audit Branch, Bureau of Government Financial Operations, U.S. Department of the Treasury, Washington, D.C. 20226, (202–634–5978).

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of December 29, 1976, at pages 56674 and 56675, there was published a notice of proposed rulemaking to amend 31 CFR Part 223 (also appearing as Department Circular 297). Interested parties were given thirty days ending on January 23, 1977, in which to submit written views or comments with regard to the amendments. As no written views or comments were received during the thirty day period, the Department finds that there is no good cause to postpone the proposed amendments' effective date. Accordingly, the proposed amendments are hereby adopted.

In addition, for additional clarity and exactness the Department finds it necessary to amend the fourth sentence of 31 CFR 223.8 by amending "N.A.I.C." to read "National Association of Insurance Commissioners." Also, in the first sentence of 31 CFR 223.9, the word "instructions" is amended to read "guidelines" for additional clarity and to provide consistency. The Department further finds that notice to the public respecting the amendments to 31 CFR 223.8 and 31 CFR 223.9 is not appropriate or necessary as their sole purpose is to clarify the regulations and the amendments have minimal public effect.

NOTE.—The Bureau of Government Financial Operations has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

Dated: February 4, 1977.

D. A. PAGLIAI,
Commissioner, Bureau of Government Financial Operations.

§ 223.3 [Amended]

1. In § 223.3: Amend "(a) If, from the evidence submitted in the manner and form herein required * * *" to read "(a) If, from the evidence submitted in the manner and form herein required, subject to the guidelines referred to in § 223.9 * * *"

2. Section 223.7 is amended to read:

§ 223.7 Investment of capital and assets.

The cash capital and other funds of every such company must be safely invested in accordance with the laws of the State in which it is incorporated and will be valued on the basis set forth in § 223.9. The Secretary of the Treasury will periodically issue instructions for the guidance of companies with respect to investments and other matters. These guidelines may be updated from time to time to meet changing conditions in the industry.

3. In § 223.8(a): Amend "Secretary of the Treasury" to read "Assistant Comptroller for Auditing" in the first sentence. The remaining sentences of § 223.8 (a) are amended to read:

§ 223.8 Financial reports.

(a) * * * On or before the last days of April, July and October of each year, every such company shall file a financial statement with the Assistant Comptroller for Auditing as of the last day of the preceding month. A form is prescribed by the Treasury for this purpose. The quarterly statement form of the National Association of Insurance Commissioners when modified to conform to the Treasury's requirements, may be substituted for the Treasury's form. The quarterly statement will be signed and sworn to by the company's president and secretary or their authorized designees.

* * * * *

4. Section 223.9 is amended to read:

§ 223.9 Valuation of assets and liabilities.

In determining the financial condition of every such company, its assets and liabilities will be computed in accordance with the guidelines contained in the Treasury's current Annual Letter to Executive Heads of Surety Companies. However, the Secretary of the Treasury may value the assets and liabilities of such companies in his discretion. Credit will be allowed for reinsurance in all classes of risks if the reinsuring company holds a certificate of authority from the Secretary of the Treasury, or has been recognized as an admitted reinsurer in accord with § 223.12.

§ 223.11 [Amended]

5. Section 223.11(b)(2)(i) is amended to read:. (i) One or more companies holding a certificate of authority from the Secretary of the Treasury as an acceptable surety on Federal bonds or one or more companies holding a certificate of authority as an acceptable reinsuring company on such bonds, or

6. In § 223.11(b)(2)(ii): Amend "Any company" to read "One or more companies."

7. In § 223.11(c)(1): Amend "of property" to read "of assets admitted by the Treasury."

8. Section 223.15 is amended to read:

§ 223.15 Paid up capital and surplus for Treasury rating purposes; how determined.

The amount of paid up capital and surplus of any such company shall be determined on an insurance accounting basis under the regulations in this part, from the company's financial statements and other information, or by such examination of the company at its own expense as the Secretary of the Treasury may deem necessary or proper.

§ 223.16 [Amended].

9. In § 223.16: Delete "a fidelity and" from its first sentence.

§ 223.17 [Amended]

10. In § 223.17: Amend "Whenever in the judgment of the Secretary of the Treasury a company is not complying with the requirements of 6 U.S.C. 6–13 and of the regulations in this part, he shall * * *" to read "Whenever it appears that a company is not complying with the requirements of 6 U.S.C. 6–13 and of the regulations in this part, the Secretary of the Treasury will * * *"

11. Section 223.18(a) is amended to read: