The principal author of this document was Todd J. Schneider, Regulations and Legal Publications Division, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

AMENDMENTS TO THE REGULATIONS

Parts 19 and 144 of the Customs Regulations (19 CFR Parts 19, 144) are amended in the following manner:

Section 19.15(g)(2) of the Customs Regulations (19 CFR 19.15(g)(2)) is amended to read as follows:

§ 19.15 Withdrawal for exportation of articles manufactured in bond; waste or byproducts for consumption.

(g) • • • • •

(2) Domestic distilled spirits transferred from a Customs bonded manufacturing warehouse, class 6, to a Customs bonded storage warehouse, class 2 or 3, in accordance with section 5521 of the Internal Revenue Code, as amended (26 U.S.C. 5521), and section 311, Tariff Act of 1930, as amended (19 U.S.C. 1311), shall be rewarehoused in accordance with the procedure for withdrawal and rewarehoused set forth in subparagraph (1) of this section. For other regulations concerning the entry and withdrawal of distilled spirits, see § 144.15 of this chapter.


The heading to § 144.15 of the Customs Regulations (19 CFR 144.15) is modified, and the section is amended by deleting paragraph (a)(3) and by adding new paragraphs (c) and (d), as follows:

§ 144.15 Entry and withdrawal from Customs warehouses of distilled spirits.

(a) Distilled spirits entered in warehouse under section 5066(a), Internal Revenue Code—

(b) Distilled spirits transferred from a manufacturing warehouse to a storage warehouse under section 5521 of the Internal Revenue Code—

(c) Distilled spirits entered under section 5214(a)(9), Internal Revenue Code—

(1) General rule. Distilled spirits may be entered into a Customs bonded storage warehouse under section 5214(a)(9), Internal Revenue Code, as amended (26 U.S.C. 5214(a)(9)), in the same manner as any other merchandise is entered for warehouse, unless otherwise provided in this section.

(2) Withdrawal only for exportation.

Distilled spirits warehoused under section 5214(a)(9), Internal Revenue Code, may be withdrawn only for the purpose of exportation, either directly or after rewarehousing at the same or another port. The distilled spirits may not be withdrawn for domestic consumption.

(d) Modification of warehouse entry bond. The recital clause of the warehouse entry bond, Customs form 7556, the general term bond, Customs form 7856, or any other appropriate bond form, shall be modified prior to its approval by the addition of the following condition: "Or, if said articles shall be withdrawn in accordance with section 5066(b), 5066(e), or 5214(a)(9), Internal Revenue Code of 1954, as amended (26 U.S.C. 5066(b), 5066(e), or 5214(a)(9)), shall be in compliance with these and all other applicable statutes and regulations, or in default thereof, if the obligors shall pay to the appropriate custom officer as liquidated damages an amount equal to the aggregate sum of double the duties plus the internal revenue tax assessable on the merchandise not so withdrawn."


R. E. CHASEN,
Commissioner of Customs.

Approved: August 18, 1978.

RICHARD J. DAVIS,
Assistant Secretary of the Treasury.
[FR Doc. 78-21473 Filed 8-25-78; 8:45 am]

[4410-09]

Title 21—Food and Drugs

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Placement of Preparations Containing Difenoxin in Combination With Atropine Sulfate Into Schedules IV and V

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This rule requires that the manufacture, distribution, dispensing, importation, and exportation of preparations combining 1 mg. difenoxin with 0.025 mg. atropine sulfate by subject to the controls applicable to narcotic substances in schedule IV of the Controlled Substances Act and that preparations combining 0.5 mg. difenoxin with 0.025 mg. atropine sulfate be subject to the controls applicable to Schedule V narcotic substances.

This rule results from a request of the Assistant Secretary for Health, Department of Health, Education, and Welfare, in behalf of the Secretary, review thereof by the Drug Enforcement Administration (DEA), review of the current drug control obligations of the United States under the United Nations Single Convention on Narcotic Drugs, 1961, as amended; subsequent publication in the Federal Register of a notice of proposed rulemaking (43 FR 27560) and review of comments submitted in response to the published notice.

EFFECTIVE DATE: Schedules IV and V control: September 27, 1978, except as otherwise provided in the supplementary information section of this order.

FOR FURTHER INFORMATION CONTACT:

Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, telephone 202-633-1368.

SUPPLEMENTARY INFORMATION: A notice was published in the Federal Register on Monday, June 26, 1978 (43 FR 27560) which proposed to amend title 21 of the Code of Federal Regulations (CFR), §§1308.14 (schedule IV) and 1308.15 (schedule V) to include combination drug products which contain 1 mg. difenoxin combined with 0.025 mg. atropine sulfate, in schedule IV, and 0.5 mg. difenoxin combined with 0.025 mg. atropine, in schedule V, should the Food and Drug Administration approve these combination products for marketing under the respective trade names Motofen and Motofen Half-Strength. All interested persons were given until July 6, 1978, to submit their comments or objections in writing regarding this proposal.

Two comments were received. The State of Rhode Island and Providence Plantations, Department of Health, Division of Drug Control, supported the proposed action. The second comment questioned the trade names assigned to the two products, and was forwarded to the Food and Drug Administration for their appropriate consideration. No other comments or objections were received, nor were there any requests for a hearing. In view thereof, and based upon the investigations and review of the Food and Drug Administration, and the July 14, 1978, Food and Drug Administration approval of the new drug application for the preparation containing 1 mg. difenoxin with 0.025 mg. atropine sulfate, the information contained in this rule is effective.

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for the products Motofen and Motofen Half-Strength, and upon the request of the Assistant Secretary in behalf of the Secretary of Health, Education, and Welfare, the Administrator of the Drug Enforcement Administration finds, pursuant to the authority delegated to him by the Act and regulations of the Department of Justice, that:

1. Preparations containing up to and including 1 mg. difenoxin in combination with at least 0.025 mg. atropine sulfate have a low potential for abuse.

2. Such difenoxin-atropine sulfate combination products have an accepted medical use in treatment in the United States.

3. The current drug control obligations of the United States under the United Nations Single Convention on Narcotic Drugs, 1961, as amended, can be met: (a) By the placement into schedule IV of the Act of combination drug products containing 1 mg. difenoxin and at least 0.025 mg. atropine sulfate, (b) by the placement into schedule V of the Act of combination drug products containing 0.5 mg. difenoxin with at least 0.025 mg. atropine sulfate.

Therefore, pursuant to section 201(d) of the Controlled Substances Act (21 U.S.C. 811(d)) and the regulations of the Drug Enforcement Administration and of the Department of Justice, the Administrator of the Drug Enforcement Administration hereby orders that §§1308.14 and 1308.15 to title 21, Code of Federal Regulations be amended to read as follows:

§1308.14 Schedule IV.

(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1 milligram of difenoxin (DEA Drug Code No. 9618) and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Penfluramine

(3) Stimulants

(4) Other substances

§1308.15 Schedule V.

(b) Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic alone:

(6) Not more than 0.5 milligram of difenoxin (DEA Drug Code No. 9618) and not less than 25 micrograms of atropine sulfate per dosage unit.

Effective Dates

As to preparations containing difenoxin 1 mg. or 0.5 mg., each in combination with at least 0.025 mg. atropine sulfate:

1. Registration. Any person who manufactures, distributes, dispenses, imports, or exports such substances 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 September 27, 1978.

2. Security. Such substances must be manufactured, distributed, and stored in accordance with §§1301.71 (b), (c), (f), 1301.74 (b), 1301.76, 1301.78 (a)-(f), 1301.75 (b) and (c), and 1301.76 of title 21 of the Code of Federal Regulations on or before September 27, 1978. From now until the effective date of this provision, manufacturers and distributors of such substances shall initiate whatever preparations are necessary in order to provide adequate security in accordance with DEA regulations so that substantial compliance with this provision can be met by September 27, 1978. 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. From and after September 27, 1978, all labels on commercial containers of, and all labeling of such substances shall comply with the requirements of §§1302.63-1302.65 and 1302.66 of title 21 of the Code of Federal Regulations. In addition, all labeling of the 1 mg. difenoxin-atropine sulfate combination shall comply with the requirements of §1302.07.

4. Inventory. Every registrant required to keep records who possesses any quantity of such substances shall take an inventory pursuant to §§1304.11-1304.19 of title 21 of the Code of Federal Regulations, of all stocks of substances on hand on September 27, 1978.

5. Records. All registrants required to keep records pursuant to part 1304 of title 21 of the Code of Federal Regulations shall do so regarding such substances commencing on the date on which the inventory of such substances is taken.

6. Reports. International Treaty obligations of the United States under the Single Convention on Narcotic Drugs, 1961, as amended, requires among other things that the United States annually report particular information as to the manufacture and distribution of narcotic drugs. To that end, the necessary information to fulfill these annual reporting requirements as they relate to the difenoxin-atropine sulfate combination products which are the subject of today's rulemaking, DEA needs to amend its existing regulations to extend current narcotic reporting requirements to those manufacturers of narcotic-controlled substances in schedule IV. Presently, the pertinent DEA regulation concerning these reporting requirements is 21 CFR §1308.38 and it currently does not require manufacturers of narcotic-controlled substances to report on such substances in schedule IV. DEA is preparing for publication in the Federal Register a notice of proposed rulemaking to amend §1308.38 to include schedule IV narcotic-controlled substances in the reporting requirements for that section. Pending such rulemaking, reporting requirements as set forth in §1304.38 for Schedule V narcotic-controlled substances shall also apply to Schedule IV narcotic-controlled substances, i.e. each person who is registered to manufacture a schedule IV narcotic preparation and whom manufactures such preparation in bulk or dosage form shall report the amount of such preparation thus manufactured in bulk or dosage form. The report shall include data presented in such a manner as to identify the particular form, strength, and trade name, if any, of the schedule IV product. For this purpose, persons filing reports shall utilize the national drug code assigned to the product under the national drug code system of the Food and Drug Administration.

7. Prescriptions. Preparations containing difenoxin 1 mg., or 0.5 mg., each combined with 0.025 mg. atropine sulfate, are required by the Food and Drug Administration to be dispensed pursuant to a prescription. All products containing 1 mg. difenoxin in combination with at least 0.025 mg. of atropine sulfate shall comply with the prescription requirements of §§1306.01-1306.07 and §§1306.21-1306.25 of title 21 of the Code of Federal Regulations beginning September 27, 1978. All products containing 0.5 mg. difenoxin in combination with at least 0.025 mg. atropine sulfate shall comply with the prescription requirements of §1306.31 beginning September 27, 1978.

8. Importation and exportation. All importation and exportation of such substances shall, on or after September 27, 1978, be required to be in com-
RULES AND REGULATIONS

Part 470, subpart A of chapter I, title 23 of the Code of Federal Regulations is amended as follows:

§ 470.107 [Amended]
1. In § 470.107(a)(1), change the citation reading "$470.2(b) (1) and (2)" to read "$470.103(b) (1) and (2)";
2. In § 470.107(a)(2), delete the words "23 CFR part 470, subpart B and with";
3. In § 470.107(d)(2), the reference "$470.3 (b), (c), and (d)" is corrected to read "$470.105 (b), (c), and (d)";
4. In § 470.107(e)(1), the reference to "$470.1(c)" is corrected to read "$470.107(c)";

§ 470.109 [Amended]
5. In § 470.109 (p)(2), (b)(2), (c)(2), (d)(2), the references to "$470.4(c)" are corrected each time to read "$470.107(b) (1)".

(Docket No. R-78-565)

HOME AND PROJECT MORTGAGES AND LOANS UNDER THE NATIONAL HOUSING ACT

Debenture Interest Rates

AGENCY: Department of Housing and Urban Development.

ACTION: Final rule.

SUMMARY: This rule change provides for an increased debenture interest rate applicable to all home and project mortgages and loans under the National Housing Act (the "Act"), as amended, except for those loans or mortgages insured under the Act's section 221(g)(34) provision, committed or endorsed on or after July 1, 1978. The Secretary of the Treasury determines debenture interest rates in accordance with established procedure and the Act. The intended effect of this rule change is to increase debenture interest rates for appropriate mortgages.

EFFECTIVE DATE: July 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Frank L. Calhoun, Office of the Chief Counsel, 202-426-0762, Federal Highway Administration, 400 Seventh Street SW., Washington, D.C. 20590, Office hours are from 7:30 a.m. to 4:15 p.m. e.t. Monday through Friday.

FEDERAL REGISTER, VOL. 43, NO. 167—MONDAY, AUGUST 28, 1978

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:
The Secretary of the Treasury has determined in accordance with the provisions of section 224 of the National Housing Act, as amended, that the interest rate for the month of May 1978 is 7.75 percent and has approved the establishment of debenture interest rates at 7.75 percent to be effective as of July 1, 1978.

The Secretary has determined that advance publication and notice and public procedure are unnecessary since the debenture interest rate is set by the Secretary of the Treasury in accordance with a procedure established by statute.

A finding of inapplicability respecting the National Environmental Policy Act of 1969 has been made in accordance with HUD procedures. A copy of this finding of inapplicability will be available for public inspection during regular business hours at the office of the rules docket clerk, Office of the General Counsel, Room 5216, Department of Housing and Urban Development, 451 7th Street SW., Washington, D.C. 20410.

Accordingly, Chapter II is amended as follows:

PART 203—MUTUAL MORTGAGE INSURANCE AND INSURED HOME IMPROVEMENT LOANS

Subpart B—Contract Rights and Obligations

1. Section 203.405 is amended to read as follows:

§ 203.405 Debenture interest rate.

Debentures shall bear interest from the date of issue, payable semiannually on the first day of January and the first day of July of each year at the rate in effect as of the day the commitment was issued, or as of the date the mortgage was endorsed for insurance, whichever rate is higher.

The following interest rates are effective for the dates listed:

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