

(2) A fee for NASA activities associated with a SSUS procurement.

(3) The price for all NASA-provided SSUS launch site services.

(c) In addition to paragraphs (a) and (b) of this section, SSUS users will reimburse NASA a share of the costs incurred by NASA for monitoring the commercial SSUS development and a share of the costs of NASA's investment in SSUS capabilities.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

Cross Reference: For a document issuing a final rule by the Drug Enforcement Administration regarding Control of Bulk Dextropropoxyphene (Non-Dosage Forms) in Schedule II as an Opiate, see FR Dec. 80-21514 appearing in the rules and Regulations section of this issue of the Federal Register.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Control of Bulk Dextropropoxyphene (Nondosage Forms) in Schedule II as an Opiate

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued as a result of international treaty obligations and imposed Schedule II opiate controls over bulk dextropropoxyphene (non-dosage forms).

EFFECTIVE DATE: The effective date for the requirements imposed by this Order is September 22, 1980, unless otherwise set forth below.

FOR FURTHER INFORMATION CONTACT: William M. Lenck, Chief Counsel, Drug Enforcement Administration, telephone number (202) 683-1276.

SUPPLEMENTARY INFORMATION: On April 17, 1980, the Secretary-General of the United Nations advised the Secretary of State of the United States that the Commission on Narcotic Drugs had decided that the drug dextropropoxyphene should be added to Schedule II of the Single Convention on Narcotic Drugs, 1961. (NAR/CL.3/1980,

G/SO 421/11(1)). Therefore, under the provisions of section 201(d)(1) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(d)(1)), the Attorney General is required to control dextropropoxyphene in the schedule deemed appropriate.

Article 29 paragraph 2(c) of the Single Convention requires that "licensed manufacturers of drugs obtain periodical permits specifying the kinds and amounts of drugs which they shall be entitled to manufacture. A periodical permit, however, need not be required for preparations." Pages 322 and 323 of the Commentary on the Single Convention on Narcotic Drugs, 1961 (prepared by the Secretary General of the United Nations in accordance with paragraph 1 of the Economic and Social Council resolution 914D (XXXIV) of August 3, 1962) make it very clear that the term "periodical permits" in Article 29 paragraph 2(c) means manufacturing quotas. Since the provisions of the controlled substances Act (21 U.S.C. 826) only provide for manufacturing quotas for Schedule I and II substances, and since dextropropoxyphene has a currently accepted medical use in treatment in the United States which precludes it being placed in Schedule I, the Drug Enforcement Administration has determined that

dextropropoxyphene should be controlled as an opiate in Schedule II. However, it should be noted that the notice from the Secretary General regarding the placing of dextropropoxyphene in Schedule II of the Single Convention does not require controls on dextropropoxyphene preparations, in addition to those required by Schedule IV of the CSA. Moreover, it should also be noted that the U.N. decision to place dextropropoxyphene in Schedule II of the Single Convention does not necessarily effect the prescription status of dextropropoxyphene in the United States since Article 2, Paragraph 2 of the Single Convention except Schedule II drugs from the prescription controls of Article 20, Paragraph 2, of the Convention.

Therefore, it is hereby determined that the appropriate method to control dextropropoxyphene at this time is to classify all bulk dextropropoxyphene (non-dosage forms) as opiates in Schedule II of the Controlled Substances Act.

Control Under Schedule II: Under the authority vested in the Attorney General by section 201(d)(1) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(d)(1)) and Delegated to the Administrator of the Drug Enforcement

Administration by § 0.100 of Title 28 of the Code of Federal Regulations and in accordance with § 1308.49 of Title 21 of the Code of Federal Regulations, the Administrator hereby orders that: Section 1308.12(c) of Title 21 of the Code of Federal Regulations be amended as follows:

§ 1308.12 [Amended]

By renumbering § 1308.12(4) through (21) as (5) through (22) and the following new item (4) is added to read as follows:

§ 1308.12 Schedule II.

* * * * *

(c) *Opiates.* Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrophan and levorpropoxyphene excepted:

* * * * *

(4) Bulk Dextropropoxyphene (non-dosage forms)—9273.

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Control Under Schedule II for Quota Purposes: The scheduling of bulk dextropropoxyphene as an opiate in Schedule II makes applicable all of the regulatory provisions relative to quotas contained in 21 CFR 1303.01 through 1303.37.

However, in order to satisfy the treaty provision that Schedule II requirements be imposed when notice is "received" from the Commission on Narcotic Drugs, all persons desiring to manufacture bulk dextropropoxyphene during the calendar year 1981 must apply for an individual manufacturing quota by September 1, 1980 and comply with all provisions of 21 CFR 1303.22 applicable thereto. For subsequent calendar years, the normal May 1 filing date in 1303.22 will apply.

Similarly, persons seeking procurement quotas for bulk dextropropoxyphene pursuant to 21 CFR 1303.12 for the calendar year 1981 must apply for such quotas by September 1, 1980. For subsequent years the normal April 1 filing date in § 1303.12 will apply.

Subsequently, DEA intends by November 1, 1980 to publish notice of the proposed aggregate production quota for bulk dextropropoxyphene for the calendar year 1981.

Control Under Schedule II for Importation Purposes: The provisions of Section 1002 of the Controlled Substances Import and Export Act (21 U.S.C. 952) only allow the importation of certain controlled substances including Schedule II substances "during an

emergency in which domestic supplies of the substance or drug are found by the Attorney General to be inadequate" (Section 1002(a)(2)(A)) or "in any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303" (Sec. 1002(a)(2)(B)). Since this final order classifies bulk dextropropoxyphene (non-dosage forms) as a narcotic drug in Schedule II, no import permits will be granted by DEA 180 days after the publication of this final order unless the required authority to import bulk dextropropoxyphene is obtained pursuant to Section 1002(a)(2)(A) or (B) and applicable regulations.

Control Under Schedule II for Exportation Purposes: Any person who intends to export bulk dextropropoxyphene (non-dosage forms) who is not registered to export Schedule II narcotic drugs must submit an application for registration to do so, pursuant to Sections 1311.21 and 1312.21 of Title 21, Code of Federal Regulations. All exportation of such bulk dextropropoxyphene shall be in compliance with 21 CFR 1312.23 which requires the registered exporter to obtain a permit from DEA for such exportation.

Collateral Controls: All of the other Schedule II controls contained in the Controlled Substances Act and applicable regulations related to penalties, registration, recordkeeping, inventories, labeling, security requirements and order forms, shall apply to bulk dextropropoxyphene (non-dosage forms). Requests for extensions of time for meeting security and labeling requirements will be considered on a case-by-case basis.

Related Matter: In a related matter concerning dextropropoxyphene, the Drug Enforcement Administration has finalized an order to classify dextropropoxyphene as a narcotic drug in Schedule IV of the CSA. This resulted in changes under the CSA related to narcotic treatment programs, export permits, importation restrictions, recordkeeping, and reporting requirements. (See Federal Register proposal of January 21, 1980, 45 FR 3923, and Final Order of June 24, 1980, 45 FR 42264). This classification resulted from the scientific and medical evaluation and recommendation of the Assistant Secretary of Health, Department of Health, Education, and Welfare (HEW), now the Department of Health and Human Services (HHS), that

dextropropoxyphene should be classified as a narcotic drug in Schedule IV of the CSA. Since this recommendation of HEW was received by DEA before the U.N. moved to place dextropropoxyphene under Schedule II of the Single Convention, DEA has requested another recommendation from HHS relative to whether the dosage forms of dextropropoxyphene containing no other active ingredients (not preparations) should be classified as narcotics in Schedule II of the CSA or as narcotics in Schedule IV of the CSA. Until such a recommendation is received from HHS, all dosage forms of dextropropoxyphene will remain in Schedule IV in the CSA.

Dated: July 14, 1980.

Peter B. Bensinger,
Administrator, Drug Enforcement
Administration.

[FR Doc. 80-21514 Filed 7-21-80; 8:45 am]
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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 7707]

Income Tax; Taxable Years Beginning After December 31, 1953; Income of Foreign Governments

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final regulations relating to the taxation of income of foreign governments. These regulations provide guidance for taxing foreign sovereigns on their income from commercial activities within the United States.

EFFECTIVE DATE: The regulations are generally effective for income of a foreign government from commercial activities within the United States derived after July 22, 1980.

FOR FURTHER INFORMATION CONTACT: Donald K. Duffy of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224, Attention: CC:LR:T (LR-106-75), 202-566-4336.

SUPPLEMENTARY INFORMATION:

Background

On August 15, 1978, the Federal Register published proposed amendments to the Income Tax Regulations (26 CFR Part 1) under section 892 of the Internal Revenue

Code of 1954 (43 FR 36111). The amendments were proposed to clarify existing regulations which neither define the term "foreign government" nor establish the types of income excluded from gross income and exempted from taxation. The proposed amendments define a foreign government to include only integral parts and controlled entities of a foreign sovereign. The proposed amendments generally provide that income derived by a foreign government from commercial activities in the United States is not income of a foreign government for purposes of the exemption under section 892.

The proposed amendments in effect provide that if a foreign sovereign separately owns and controls an entity which is not an integral part and which does not constitute a "controlled entity", such an entity is taxed on all of its commercial and noncommercial income under appropriate Internal Revenue Code provisions. The amendments define the term "controlled entity", and in most respects the definition parallels the requirements of Rev. Rul. 75-290, 1975-2 C. B. 290, relating to certain organizations created by foreign governments that are eligible for the section 892 exemption.

The Federal Register published a notice of a public hearing on November 6, 1978 (43 FR 51648). The hearing was held on January 23, 1979.

After consideration of all relevant matters presented by interested persons regarding the proposed amendments, they are adopted as revised by this Treasury decision.

This document also reserves paragraph (c)(2)(i)(d) and (e) of § 1.892-1. These paragraphs will provide rules for determining whether loans or net leases are to be considered investments. A notice of proposed rulemaking is being published contemporaneously with this Treasury decision setting forth those rules.

Distinction Between Integral Parts and Separate Entities

Comments from the public questioned whether it was appropriate to draw a distinction between integral parts and separate entities of a foreign sovereign under § 1.892-1(b) for purposes of the definition of the term "foreign government". Section 1.892-1(b) is revised in the final regulations. The revision places less emphasis on both the form of the entity that exercises foreign governmental authority and the extent of its commercial activity in the United States.