21 CFR Part 1308

Classification of Dextropropoxyphene as a Narcotic Drug in Schedule IV of the Controlled Substances Act

Cross Reference: For a document issuing a final rule by the Drug Enforcement Administration regarding Classification of Dextropropoxyphene as a Narcotic Drug in Schedule IV of the Controlled Substances Act, See FR Doc. 18841 appearing on page 42264 of this issue of the Federal Register.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Classification of Dextropropoxyphene as a Narcotic Drug in Schedule IV of the Controlled Substances Act

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule, in addition to the Schedule IV controls which are currently imposed upon dextropropoxyphene, involves the following: (1) The drug's control by this Order as a Schedule IV narcotic drug, (2) restriction on using the drug in Narcotic Treatment Programs, (3) recordkeeping by practitioners who dispense other than by prescribing or administering the drug, (4) requirements for export permits to export the drug from the United States, and (5) the prohibition of importation of the drug into the United States.

EFFECTIVE DATE: The effective date for the requirements imposed by this Order is July 24, 1980, unless otherwise set forth below in the supplementary information section.

FOR FURTHER INFORMATION CONTACT: William M. Lenck, Chief Counsel, Drug Enforcement Administration, telephone number (202) 633–1276.

SUPPLEMENTARY INFORMATION: On January 21, 1980, the Administrator of the Drug Enforcement Administration published a notice of proposed rulemaking to amend § 1308.14 of Title 21 of the Code of Federal Regulations (CFR) by classifying dextropropoxyphene as a narcotic. This classification matter originated with the Assistant Secretary of Health, Department of Health, Education and Welfare and was contained in his scientific and medical evaluation and recommendations concerning dextropropoxyphene which he provided to the Administrator of the Drug Enforcement Administration in a letter dated September 7, 1979, along with his recommendation that then-pending petitions to control dextropropoxyphene in Schedule II of the Controlled Substances Act be denied. The Assistant Secretary's proposal set forth an analysis of dextropropoxyphene as a narcotic; and to supplement that analysis, Dr. J. Richard Crout, Director, Bureau of Drugs, Food and Drug Administration, provided additional evidence in support of the position that dextropropoxyphene is an opiate, and hence, a narcotic drug, as defined in Sections 102 (17) and (16) of the Controlled Substances Act [21 U.S.C. 802 (17), (16)]. The notice published on January 21, 1980 (45 FR 3923) provided an opportunity for all interested persons to submit comments on the matter no later than February 20, 1980.

One letter commenting on the proposed rule was received by the Drug Enforcement Administration from Eli Lilly and Company. Lilly did not oppose the classification of dextropropoxyphene as a narcotic within the meaning of the Controlled Substances Act.

Lilly included in its comment its observation concerning the dependence producing characteristics of dextropropoxyphene (which it markets as Darvon) as compared to other narcotics such as morphine and codeine, which are in Schedule II. With its observations, Lilly also provided DEA with a copy of a submission it earlier presented to the FDA Drug Abuse Advisory Committee in April, 1979, in which Lilly's observations and dependence data compares dextropropoxyphene with morphine and codeine, and in which they claim that dextropropoxyphene is quantitatively, but not qualitatively, less able to produce or sustain dependence than morphine and codeine.

Although no other comments on the notice of proposed rulemaking concerning dextropropoxyphene were received, it should be noted that the control of dextropropoxyphene as a narcotic has gained international attention. 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 (CND) has decided to include dextropropoxyphene in Schedule II of the Single Convention on Narcotic Drugs (NAR/CL.3/1980, G/SO 421/11(1)). The United States, as a party to that Convention, is required to impose "periodical permits" (quotas) on the domestic manufacture of dextropropoxyphene. Quotas are a statutory and regulatory control measure imposed by the federal Controlled Substances Act and DEA regulations only upon controlled substances in Schedule I or II.

The Administrator of the Drug Enforcement Administration is issuing this final order presently, mindful that this action might well be succeeded by DEA imposing further domestic controls upon dextropropoxyphene to the extent compelled by the United States international obligations as a result of dextropropoxyphene being included in Schedule II of the Single Convention on Narcotic Drugs.

Control as Narcotic Drug

Accordingly, based upon the Assistant Secretary for Health's medical and scientific evaluation of dextropropoxyphene as a narcotic, the Administrator finds that dextropropoxyphene is an opiate and therefore a narcotic drug as defined in Sections 102 (17) and (16) of the Controlled Substances Act [21 U.S.C. 802 (17), (16)]. Hence, 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 by deleting subsection (f)(1) in its entirety, renumbering existing subsection (f)(2) as (f)(1), and by adding a new subsection (b)(2) to read:

§ 1308.14 Schedule IV.

* * * * *

(b) *Narcotic Drugs.* * * *

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(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane) 9273

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Narcotic Requirements and Effective Dates

DEA currently requires all manufacturers, distributors, practitioners, importers and exporters of dextropropoxyphene to comply with all applicable Schedule IV controlled substances requirements concerning registration, security, labeling and packing, inventory and recordkeeping, prescriptions, importation and exportation. The classification of dextropropoxyphene as a narcotic will add the following requirements:

1. *Narcotic Treatment Programs.* Under the provisions of the Narcotic Treatment Act of 1974 (Pub. L. 93–281, May 14, 1974) and the regulations of

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DEA and FDA, narcotic treatment programs are currently using methadone, a Schedule II narcotic drug, in detoxification and maintenance treatment. However, a smaller number of practitioners have also been using dextropropoxyphene to treat drug dependent persons.

The classification of dextropropoxyphene as a narcotic drug in Schedule IV by this final order will result in practitioners currently treating persons for drug dependence with dextropropoxyphene no longer being able to do so since its status as a schedule IV narcotic drug places it under the provisions of the Narcotic Treatment Act of 1974 and the applicable DEA and FEA regulations. Since the only drug authorized to be used under the FDA regulations (21 CFR 291) is methadone, practitioners currently using dextropropoxyphene to treat drug dependent persons must terminate such activity within 120 days of the publication of this order.

Two possible alternatives available within the 120 day period are for the patients involved to obtain treatment in an existing methadone program or for the concerned practitioner to seek FDA authority to commence a methadone treatment program.

2. *Records.* Any person registered as a practitioner to dispense dextropropoxyphene as a Schedule IV narcotic, is required to keep records pursuant to 21 CFR 1304.21 and 1304.28 and shall maintain such records on dextropropoxyphene. Registered practitioners whose dispensing actitivies of dextropropoxyphene are limited to administering or prescribing are not affected by these provisions (21 CFR 1304.03(b)).

3. *Exportation.* Any person who intends to export dextropropoxyphene who is not registered to export Schedule IV narcotic drugs must submit an application for registration to do so, pursuant to §§ 1311.21 and 1312.21 of Title 21, Code of Federal Regulations. All exportation of dextropropoxyphene shall be in compliance with 21 CFR 1312.23 which requires the registered exporter to obtain a permit from DEA for such exploration.

4. *Importation.* 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 any narcotic drug in Schedule IV "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 dextropropoxyphene as a narcotic drug in Schedule IV, and no findings have been requested or made relative to providing authority to import dextropropoxyphene when classified as a Schedule IV narcotic drug, no import permits will be granted by DEA 180 days after the publication of this final order unless the required authority to import dextropropoxyphene is obtained pursuant to Section 1002(a)(2) (A) or (B) and applicable regulations.

(Secs. 201, 202, 501(b), 84 Stat. 1245, 1246, 1248, 1249, 1250, 1251, 1252, 1271, 21 U.S.C. 811, 812, 871(b))

Dated: June 17, 1980.

Peter B. Bensinger,

Administrator, Drug Enforcement Adminstration.

[FR Doc. 80-18641 Filed 6-23-80; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL-1521-8]

Oregon; Approval and Promulgation of the Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: By this notice, EPA today announces its approval of portions of the State Implementation Plan (SIP) for Oregon which were received by EPA on June 27 and July 6, 1979. EPA is also taking final action to conditionally approve other elements of Oregon's SIP revision. In accordance with conditional approval, the State of Oregon is required to submit to EPA materials to satisfy the various conditions within six months from the date of this publication. These plan revisions were prepared by the State of Oregon to meet the requirements of Part D (Plan Requirements for Non-attainment Areas) of the Clean Air Act (hereafter referred to as the Act), as amended in August 1977 (42 U.S.C. 1857 et seq.).

EFFECTIVE DATE: June 24, 1980.

FOR FURTHER INFORMATION CONTACT: Michael J. Schultz, Coordination and Planning Section, M/S 625, Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Seattle, WA 98101. Telephone No. (206) 442-1226, FTS 399-1226.

SUPPLEMENTARY INFORMATION:

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I. INTRODUCTION

EPA finds that good cause exists for making the action taken in this notice immediately effective for the following reasons: (1) Implementation plan revisions are already in effect under State law and EPA approval poses no additional regulatory burden, and (2) EPA has a responsibility under the Act to take final action on the portion of the SIP which addresses Part D requirements by July 1, 1979 or as soon thereafter as possible.

This notice follows the January 21, 1980 issue of the Federal Register (45 FR 3929), wherein EPA published a notice of proposed rulemaking which described the nature of the Part D SIP revisions, discussed certain provisions of the Oregon Part D SIP revisions which in EPA's judgment did not comply with the requirements of the Act, and requested public comment. State and local agencies of Oregon submitted official responses to the proposed rulemaking. No other official comments specific to this rulemaking were received.

The EPA has reviewed comments received on the proposed rulemaking and is taking the following actions:

1. *Approval.* Carbon monoxide (CO) attainment plans for the Portland, Salem, Eugene-Springfield, and Medford-Ashland non-attainment areas.

2. *Conditional Approval.* (a) Ozone (O_3) attainment plans for the Portland, Salem, and Medford-Ashland non-

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