PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the August 19, 1985, final rule. Accordingly, the amendments promulgated thereby became effective September 19, 1985.

Dated: October 29, 1985.

Mervin H. Shumate,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 85–26206 Filed 11–1–85; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances: Removal of Nalmefene From Control

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This is a final rule which removes the substance, nalmefene, and its salts from control under the Controlled Substances Act (21 U.S.C. 801 et seq.). Chemically, nalmefene is 17-(cyclopropylmethyl)-4,5-epoxy-6-methylenemorphinan-3,14-diol. Nalmefene has been a Schedule II narcotic by virtue of its derivation from the Schedule II opioid thebaine. The ruling results from the Administrator of the Drug Enforcement Administration finding, based largely upon the recommendation of the Acting Assistant Secretary for Health, that nalmefene does not have sufficient potential for abuse or abuse liability to justify its continued control in any schedule.

EFFECTIVE DATE: November 4, 1985.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 633–1366.

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

A notice was published in the **Federal Register** on May 31, 1985 (50 FR 23144) proposing the removal of nalmefene and its salts from Schedule II of the Controlled Substances Act (CSA) (21 U.S.C. 812(c) Schedule II(a)(1); § 1308.12(b)(1), Title 21 of the Code of Federal Regulations (CFR)). All interested persons were given until July 30, 1985, to submit their objections, comments or requests for a hearing regarding the proposal. No objections were received nor were there any requests for a hearing. One comment was received from a manufacturer of opium derivatives. It expressed support for the proposed action and concern that the uncontrolled importation of decontrolled opiate derivatives manufactured from controlled substances will foster widespread opiate raw material production; therefore, the international controls on narcotic substances would be weakened by adding to the current, large oversupply of the narcotics. Taking into consideration these views, the investigations of the Drug Enforcement Administration and the scientific and medical evaluation and recommendation of the Secretary of the Department of Health and Human Services, received pursuant to 21 U.S.C. 811(b), the Administrator finds that there currently does not exist evidence that nalmefene possesses sufficient potential for abuse to justify its continued control in any schedule of the CSA.

Therefore, under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR 0.100), the Administrator hereby orders that 21 CFR 1308.12(b)(1) be amended by removing nalmefene and its salts from control.

Pursuant to 5 U.S.C. 605(b), the Administrator hereby certifies that the decontrol of nalmefene will have no adverse impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96–354). In addition, nalmefene has not been approved by the Food and Drug Administration for use in medical treatment or to have accepted safety for use as a drug or other substance under medical supervision in the United States.

In accordance with the provisions of 21 U.S.C. 811(a), this proposal to remove nalmefene from Schedule II is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and as such have been exempted from the consultation requirements of Executive Order 12291.

PART 1308—[AMENDED]

Accordingly, 21 CFR Part 1308 is amended as follows:

1. The authority citation for Part 1308 continues to read as follows:

Authority: Secs. 201, 202, 501(b), 84 Stat. 1245, 1246, 1247, 1248, 1249, 1250, 1251, 1252, 1271; 21 U.S.C. 811, 812, 871(b).

2. Section 1308.12 is amended by revising paragraph (b)(1) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, dextrorphan, nalbuphine, nalmefene, naloxone, and naltrexone, and their respective salts, but including the following:

(1) Raw opium	9600
(2) Opium extracts	9610
(3) Opium fluid	9620
(4) Powdered opium	9639
(5) Granulated opium	9640
(6) Tincture of opium	9630
(7) Codeine	9050
(8) Ethylmorphine	9190
(9) Etorphine hydrochloride	9059
(10) Hydrocodone	9193
(11) Hydromorphone	9150
(12) Metopon	9260
(13) Morphine	9300
(14) Oxycodone	9143
(15) Oxymorphone	9652
(16) Thebaine	9333

* * * * *

Dated: October 29, 1985.

John C. Lawn,

Administrator, Drug Enforcement Administration.

[FR Doc. 85–26124 Filed 11–1–85; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Federal Highway Administration

23 CFR Part 1204

[NHTSA Docket No. 84–08; Notice 2]

Uniform Standards for State Highway Safety Program

AGENCY: National Highway Traffic Safety Administration (NHTSA),