DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Placement of Carfentanil Into Schedule II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to place carfentanil, a narcotic substance, into Schedule II of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This action follows receipt of a letter from the Associate Commissioner for Health Affairs, Food and Drug Administration (FDA), notifying DEA that carfentanil has received final approval for marketing as a new animal drug. This rule imposes the regulatory controls and criminal sanctions of a Schedule II narcotic substance under the CSA on the manufacture, distribution, importation and exportation of carefentanil.

EFFECTIVE DATE: October 28, 1988.

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

SUPPLEMENTARY INFORMATION: A notice was published in the **Federal Register** on January 12, 1988 (53 FR 743) proposing that carfentanil be placed into Schedule II of the CSA. Interested persons were given until February 11, 1988 to submit comments or objections regarding the proposal. No correspondence of any kind was received regarding the proposal. Furthermore, according to the September 30, 1988 letter from the Associate Commissioner for Health Affairs, FDA, the new animal drug application for carfentanil has been approved.

Based on the scientific and medical evaluation and recommendation contained in the November 12, 1987 letter from the Assistant Secretary for Health, Department of Health and Human Services, the Administrator of DEA, pursuant to the provisions of 21 U.S.C. 811 (a) and (b), finds that:

(1) Carfentanil has a high potential for abuses;

(2) Carfentanil has a currently accepted veterinary medical use in treatment in the United States; and

(3) Abuse of carfentanil may lead to severe pyschological or physical dependence.

The above findings are consistent with the placement of carfentanil into Schedule II of the CSA. The Administrator further finds that carfentanil is an opiate as defined in 21 U.S.C. 802(18) since it has an addiction-forming and addiction-sustaining liability similar to morphine. Consequently, carfentanil is a narcotic since the definition of narcotic, as stated in 21 U.S.C. 802(17)(A), includes: "Opium, opinates, derivatives of opium and opiates."

Regulations that are effective on October 28, 1988, and imposed on carfentanil are as follows:

1. *Registration.* Any person who manufactures, distributes, engages in research, imports or exports carfentanil or who proposes to engage in carfentanil's manufacture, distribution, importation, exportation or research shall obtain a registration to conduct that activity by October 28, 1988, pursuant to Part 1301 of Title 21 of the Code of Federal Regulations.

2. *Security.* Carfentanil must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72(a)(c)(d), 1301.73, 1301.74, 1301.75(b)(c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and packaging.* All labels on commercial containers of, and all labeling of, carfentanil which is packaged and distributed after October 28, 1988, shall comply with the requirements of Sections 1302.03–1302.05 and 1302.07–1302.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* Quotas for carfentanil are established pursuant to Part 1303 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Registrants possessing carfentanil are required to take inventories pursuant to Section 1304.04 and Sections 1304.11–1304.19 of Title 21 of the Code of Federal Regulations.

6. *Records.* All registrants must keep records pursuant to Section 1304.04 and Sections 1304.21–1304.29 of Title 21 of the Code of Federal Regulations.

7. *Reports.* All registrants are required to file reports pursuant to Sections 1304.31–1304.41 of Title 21 of the Code of Federal Regulations.

8. *Order Forms.* Each distribution of carfentanil requires the use of an order form pursuant to Part 1305 of Title 21 of the Code of Federal Regulations.

9. *Prescriptions.* As carfentanil has been approved by the FDA for use in veterinary medical treatment, the drug may be dispensed by prescription. Prescriptions for carfentanil are to be issued pursuant to Sections 1306.01–1306.07 and Sections 1306.11–1306.15.

10. *Importation and Exportation.* All importation and exportation of carfentanil shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

11. *Criminal Liability.* Any activity with carfentanil not authorized by or in violation of the CSA or the Controlled Substances Import and Export Act continues to be unlawful. on October 28, 1988, carfentanil for the purposes of criminal liability shall be treated as a Schedule II narcotic controlled substance.

12. *Other.* In all other respects, this order is effective on October 28, 1988.

Pursuant to Title 5, United States Code, Section 605(b), the Administrator certifies that the scheduling of carfentanil, as ordered herein, will not have a significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96–354). Carfentanil is being placed into Schedule II following its approval to be marketed as a narcotic anesthetic for use in veterinary clinics specializing in big game control. This rule will cause such establishments to handle carfentanil in a manner identical to that in place for other Schedule II products.

In accordance with the provisions of section 201(a) of the CSA (21 U.S.C. 811(a)), this scheduling action 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 (46 FR 13193). This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this matter does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

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

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 DEA by regulations of the Department of Justice (28 CFR Part 0.100), the Administrator hereby orders that 21 CFR Part 1308 be amended as follows:

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PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b).

§ 1308.12 [Amended]

2. Paragraph (c) of § 1308.12 is amended by redesignating the existing paragraphs (c)(6) through (c)(24) as (c)(7) through (c)(25) and adding a new paragraph (c)(6) as follows:

§ 1308.12 Schedule II.

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(c) * * *

(6) Carfentanil—9743

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John C. Lawn,

Administrator, Drug Enforcement Administration.

Dated: October 19, 1988.

[FR Doc. 88-24974 Filed 10-27-88; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 81

[Docket No. 76N-0366]

Provisional Listing of FD&C Red No. 3 in Cosmetics and Externally Applied Drugs, and of its Lakes in Food, Drugs, and Cosmetics; Postponement of Closing Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of FD&C Red No. 3 for use in coloring cosmetics and externally applied drugs and of the lakes of this color additive for use in coloring food, drugs, and cosmetics. The new closing date for the provisional listing of this color additive will be June 30, 1989. This postponement will permit the uninterrupted use of this color additive while FDA receives and evaluates new information on FD&C Red No. 3 and prepares appropriate **Federal Register** documents for the regulation of this color additive.

EFFECTIVE DATE: October 28, 1988, the new closing date for FD&C Red No. 3 and its lakes will be June 30, 1989.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5676.

SUPPLEMENTARY INFORMATION:

I. Backgrond

Under Title II of the Color Additive Amendments of 1960 (the transitional provisions) (Pub. L. 86-618, sec. 203 (21 U.S.C. 376, note)), FDA is authorized to postpone the closing date of the provisional listing of a color additive. The agency's discretion in issuing such postponements is limited in only two respects: "Such postponements must be consistent with the public health, and the Commissioner must judge that the scientific investigations are going forward in good faith and will be completed as soon as reasonably practicable." (*McIlwain* v. *Hayes*, 690 F.2d 1041, 1047 (DC Cir. 1982) and *Public Citizen* v. *Department of Health and Human Services*, No 86-5150 (decided in *Public Citizen* v. *Young*, 831 F.2d 1108, 1122 (DC Cir. 1987)).)

In the **Federal Register** of August 30, 1988 (53 FR 33147), FDA proposed to postpone the closing date of FD&C Red No. 3. FDA proposed this postponement to allow the agency time to complete its evaluation of data from a new rat study being conducted by the Certified Color Manufacturers' Association (CCMA). This study is designed to demonstrate that FD&C Red No. 3 has no direct effect on the thyroid, i.e., that it operates through a secondary mechanism. This postponement also allows the agency to complete its evaluation of the sale and use data on FD&C Red No. 3, to make a final decision with respect to the status of FD&C Red No. 3 under the color additive amendments, and to prepare the appropriate **Federal Register** documents for the regulation of this color additive. The agency concluded that these activities can be accomplished by June 30, 1989.

In response to the proposal, FDA received 34 comments from members of Congress, trade associations, food growers, food processors, a packer, a marketer, and a public interest group. Thirty-three comments supported the proposed postponement of the closing date. One comment (from Public Citizen, a public interest group) opposed the postponement.

FDA has carefully considered these comments and has also considered, in light of the comment opposing the proposed extension, whether this extension is appropriate under the standards set forth in *McIlwain* v. *Hayes*. The summary of the comments and the conclusions that the agency has reached follow:

II. Comments

A. Comments Supporting the Proposed Extension

The agency received 33 comments supporting the proposed extension. Five comments (from a cherry grower, two processors, a marketer, and a trade association) noted that June 30, 1989, is in the middle of the cherry growing season and requested an extension of the provisional listing for FD&C Red No. 3 until the end of the season (September 1, 1989).

The agency acknowledges the concern expressed by these five comments. However, the agency believes that it is important to resolve the issues relating to FD&C Red No. 3 as expeditiously as possible. The agency concludes that postponement of the closing date to June 30, 1989, provides a reasonable time period for the agency to receive and evaluate the new information from the CCMA study, to decide whether FD&C Red No. 3 can be permanently listed, and to develop the appropriate **Federal Register** documents. Thus, based on information currently available to it, the agency concludes that it is reasonably practicable for these steps to be completed by June 30, 1989. Further, the agency concludes that postponement of the closing date for the convenience of the users of the color additive would be inconsistent with the transitional provisions of the Color Additive Amendments.

B. Comment Opposing the Proposed Extension

The comment opposing the postponement asserted that FDA has provided no valid justifications for its extension of the provisional listing of FD&C Red No. 3. The comment further asserted that this extension is designed to delay, rather than to resolve, the provisional listing of the color additive. The comment based its opposition to the postponement on its brief filed in the United States Court of Appeals for the District of Columbia Circuit in *Public Citizen* v. *Department of Health and Human Services, supra*, and its July 19, 1988, comments objecting to the agency's previous extension of the provisional listing of FD&C Red No. 3 to August 30, 1988.

In opposing the proposed postponement of the closing date for provisional listing for FD&C Red No. 3, the comment listed four points. Although each is discussed separately below, most of the points are dealt with by the decision in *Public Citizen* v. *Young, supra*, 831 F.2d at 1122-1123. That decision establishes that postponement

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