Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rulemaking prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Parts 1301, 1304, 1305]

ETORPHINE HYDROCHLORIDE AND DIPRENORPHINE

Proposed Controls

The Drug Enforcement Administration on November 23, 1973, published a notice in the FEDERAL REGISTER (38 FR 32262) proposing the transfer of etorphine hydrochloride from Schedule I to Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 821 et seq.). A final notice transferring etorphine hydrochloride to Schedule II is published this date in the FEDERAL REGISTER.

Etorphine hydrochloride is a derivative of the opium alkaloid Thebaine. It is a morphine-like agent with an analgesic potency, depending on test methods, that is 80 to 1,000 times greater than morphine. Because of its ability to produce narcosis at very low doses, etorphine hydrochloride has been approved by the Food and Drug Administration for the immobilization of wild and exotic animals (38 FR 15050).

Diprenorphine, a Schedule II controlled substance, is the only effective antidote to reverse the state of narcosis produced by etorphine hydrochloride. Diprenorphine has been approved by the Food and Drug Administration as an etorphine hydrochloride antagonist. (38 FR 15050.)

Due to the high potential for abuse of these substances with their limited medical uses and ability to produce severe psychological and physical dependence, the Drug Enforcement Administration, in concert with the Special Action Office of Drug Abuse Prevention and the Food and Drug Administration promulgated and agreed to specific procedures relating to their distribution. The American Cyanamid Co. (the holder of the New Animal Drug Application) and the D–M Pharmaceuticals Inc. (the firm marketing the product under the New Animal Drug Application) have agreed to abide by the following procedures to ensure against the abuse, diversion or misuse of these substances:

1. The distribution of etorphine hydrochloride and diprenorphine is restricted to licensed veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and/or research. Only veterinarians who are directly engaged in zoo and exotic animal practice, wildlife management programs, and/or research may obtain etorphine hydrochloride or diprenorphine. These substances will not be available to other practicing veterinarians or other practitioners (except for authorized researchers). The Food and Drug Administration has restricted the use of etorphine hydrochloride and diprenorphine by or on the order of a licensed veterinarian. The Drug Enforcement Administration shall transmit additional information to the Food and Drug Administration indicating its willingness to permit other qualified persons to use these substances if the Food and Drug Administration deems it proper and changes the labelling of the substances.

2. In order to provide maximum security in the distribution, storage and use of etorphine hydrochloride and diprenorphine, all registrants submitting order forms for these substances will be checked by the Drug Enforcement Administration to ensure that they are properly authorized to handle these substances and are prepared to adhere to the special safeguards set forth in the regulations. [An amendment to § 1301.74 (g) to implement this requirement is proposed below.]

3. Registrants handling etorphine hydrochloride or diprenorphine shall be required to store these substances in a safe or steel cabinet equivalent to a United States Government Class V security container. The storage of these substances will be limited to reasonable quantities to avoid increased vulnerability of theft. [An amendment to § 1301.75(d) of the regulations to implement this requirement is proposed below.]

4. The order forms submitted by registrants desiring to purchase etorphine hydrochloride or diprenorphine must contain those substances only. If an order form for etorphine hydrochloride and diprenorphine is submitted to the supplier containing any other controlled substance it shall not be filled. [Amendments to § 1305.16 (Special procedure for filling certain order forms) and § 1305.06 (Procedure for executing order forms) to implement these requirements are proposed below.]

5. The supplier of etorphine hydrochloride and diprenorphine must maintain order forms for those substances separately from all other order forms and records required to be maintained by the registrant pursuant to 21 CFR Part 1304. [An amendment to § 1305.13 (Preservation of order forms) to implement this requirement is proposed below.]

6. An additional reporting requirement is imposed upon the manufacturer of etorphine hydrochloride and diprenorphine. The manufacturer is required to forward a copy of all order forms received for these subtances to the Drug Enforcement Administration for inspection on a weekly basis. [An amendment to § 1304.38(d) (Reports from manufacturers of bulk materials or dosage units) to implement this requirement is proposed below.]

7. Etorphine hydrochloride and diprenorphine shall only be shipped to the purchaser at the location printed by the Administration on the order form. Shipment is to be made by the most secure method using substantial packaging with no markings on the outside. [An amendment to § 1305.16(b)(ii) to implement this requirement is proposed below.]

Therefore, under the authority vested in the Attorney General by Sections 301, 307, 308, 501(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 821, 827, 828 and 871(b)), and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 21 of the Code of Federal Regulations, the Administrator proposes that:

1. Section 1301.74 of Title 21 of the Code of Federal Regulations be amended by adding a new paragraph (g) to read as follows:

§ 1301.74 Other Security Controls for Non-practitioners.

* * * * *

(g) Before the initial distribution of etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substance(s) by contacting the Drug Enforcement Administration.

* * * * *

2. Section 1301.75 of Title 21 of the Code of Federal Regulations be amended by adding a new paragraph (d) to read as follows:

§ 1301.75 Physical Security Controls for Practitioners.

* * * * *

(d) Etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

* * * * *

3. Section 1304.38 of of Title 21 of the Code of Federal Regulations be amended by adding a new paragraph (d) to read as follows:

§ 1304.38 Reports from the Manufacturers of Bulk Materials or Dosage Units.

* * * * *

(d) Registrants manufacturing etorphine hydrochloride or diprenorphine shall, on a weekly basis, forward a copy of

the order forms received for these substances to the Administration.

* * * * *

4. Section 1305.06(b) of Title 21 of the Code of Federal Regulations be amended by adding a new phrase to read as follows:

§ 1305.06 Procedure for Executing Order Forms.

* * * * *

(b) Only one item shall be entered on each numbered line. There are five lines on each order form. If one order form is not sufficient to include all items in an order, additional forms shall be used. Order forms for etorphine hydrochloride and diprenorphine shall contain only these substances. The total number of items ordered shall be noted on that form in the space provided.

* * * * *

5. Part 1305 of Title 21 of the Code of Federal Regulations be amended by adding a new § 1305.16 to read as follows:

§ 1305.16 Special Procedure for Filling Certain Order Forms.

(a) The purchaser of etorphine hydrochloride or diprenorphine shall submit copy 1 and 2 of the order form to the supplier and retain copy 3 in his own files.

(b) The supplier, if he determines that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs and/or research and authorized by the Administrator to handle these substances shall fill the order in accordance with the procedures set forth in § 1305.09 except that: (i) Order forms for etorphine hydrochloride and diprenorphine shall only contain these substances in reasonable quantities and (ii) the substances shall only be shipped to the purchaser at the location printed by the Administration upon the order form under secure conditions using substantial packaging material with no markings on the outside which would indicate the content.

* * * * *

6. Section 1305.13 be amended by adding a new paragraph (d) to read as follows:

§ 1305.13 Preservation of Order forms.

* * * * *

(d) The supplier of etorphine hydrochloride and diprenorphine shall maintain order forms for these substances separately from all other order forms and records required to be maintained by the registrant.

In order to protect the public welfare by ensuring that etorphine hydrochloride and diprenorphine are manufactured, distributed, stored, and used in a proper manner, the foregoing provisions shall be effective on the date of publication as interim procedures until the proposals are finalized.

All interested persons are invited to submit their comments and objections in writing regarding this proposal. These comments or objections should state with particularity the issues concerning which the person desires to be heard. Comments and objections should be submitted in quintuplicate to the Hearing Clerk, Office of Chief Counsel, Drug Enforcement Administration, Department of Justice, Room 611, 1405 Eye Street NW., Washington, D.C. 20537, and must be received no later than April 26, 1974.

In the event that an interested party submits objections to this proposal which present reasonable grounds for this rule not to be finanlized and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail that a hearing will be held at the time and place set forth in the letter. A notice of hearing will simultaneously be published in the FEDERAL REGISTER. If objections submitted do not present such reasonable grounds, the party will so be advised by registered mail.

If no objections presenting reasonable grounds for a hearing on the proposal are received within the time limitations and all interested parties waive or deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, and after giving consideration or written comments, issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Dated: March 25, 1974.

JOHN R. BARTELS, Jr.,
Administrator,
Drug Enforcement Administration.

[FR Doc.74-7277 Filed 3-28-74;8:45 am]

DEPARTMENT OF LABOR

Office of Federal Contract Compliance

[41 CFR Parts 60-1, 60-50]

RELIGIOUS ENTITIES

Proposed Exemption

Notice is hereby given that pursuant to Executive Order 11246 (30 FR 12319), as amended by Executive Order 11375 (32 FR 14303), the Department of Labor proposes to clarify the employment obligations of religious corporations, associations, educational institutions and societies under Executive Order 11246 (as amended). This proposal is intended to establish consistency between the religious exemption provisions of section 702 of the Civil Rights Act of 1964, as amended by the Equal Employment Opportunity Act of 1972, and the rules and regulations of the Office of Federal Contract Compliance.

This proposed rulemaking concerns matters relating to public contracts. While public participation is not required, the Department of Labor, in keeping with the spirit of 5 U.S.C. 553, invites submission of written comments, suggestions or objections regarding these proposed amendments to Mr. Philip J. Davis, Director, Office of Federal Contract Compliance, U.S. Department of Labor, 14th Street and Constitution Avenue, NW., Washington, D.C. 20210, on or before April 29, 1974.

In consideration of the foregoing, it is proposed to amend Chapter 60 of Title 41, Code of Federal Regulations, as follows:

PART 60-1—OBLIGATIONS OF CONTRACTORS AND SUBCONTRACTORS

1. A new paragraph (a)(5) is proposed to be added to § 60-1.5 reading as follows:

§ 60-1.5 Exemptions.

(a) * * *

(5) *Contracts with religious entities.* The requirements of the equal opportunity clause shall not apply to a religious corporation, association, educational institution or society with respect to the employment of individuals of a particular religion to perform work connected with the carrying on by such corporation, association, educational institution, or society of its activities.

* * * * *

PART 60-50—GUIDELINES ON DISCRIMINATION BECAUSE OF RELIGION OR NATIONAL ORIGIN

2. A new paragraph (e) is proposed to be added to § 60-50.1 reading as follows:

§ 60-50.1 Purpose and scope.

* * * * *

(e) Nothing contained in this Part 60-50 is intended to supersede or otherwise limit the exemption set forth in § 60-1.5(a)(5) of this chapter for contracts with religious entities.

Signed at Washington, D.C., this 19th day of March 1974.

PETER J. BRENNAN,
Secretary of Labor.

BERNARD E. DELURY,
Assistant Secretary for Employment Standards.

PHILIP J. DAVIS,
Director, Office of Federal Contract Compliance.

[FR Doc.74-7318 Filed 3-28-74;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 1]

HYPOALLERGENIC COSMETICS

Proposed Definition

Correction

In FR Doc. 74-4305 appearing at page 7287 as the Part IV of the issue of Monday, February 25, 1974, make the following changes:

1. In the third column on page 7291, in the second line of paragraph 5., the word "Operations" should read "Opinions".

2. In column three on page 7292, in the second from the last paragraph, the date "April 26, 1973" should read "April 26, 1974".