

3. Deadlines

A. Applications shall be considered as meeting a deadline if they are either:

1. Received at the above address on or before the deadline date; or
2. Sent on or before the deadline date to the above address, and received in time for the review process. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be accepted as proof of timely mailing.)

B. Applications which do not meet the criteria in 3.A.1. or 3.A.2. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address and phone number and will need to refer to Announcement 565. You will receive a complete program description, information on application procedures, and application forms.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Georgia L. Jang, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E13, Atlanta, GA 30305, telephone (404) 842-6814. Programmatic technical assistance may be obtained from Roy M. Fleming, Sc.D., Associate Director for Grants, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Building 1, Room 3053, Mailstop D30, Atlanta, GA 30333, telephone (404) 639-3343.

Please refer to Announcement 565 when requesting information and submitting an application.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the "Introduction" through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: May 12, 1995.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-12201 Filed 5-17-95; 8:45 am]

BILLING CODE 4163-19-P

Food and Drug Administration

[Docket No. 95N-0123]

Drug Export; Revia™ (Naltrexone Hydrochloride (HCl)) 50 Milligrams (mg) Film-Coated Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Dupont Merck has filed an application requesting approval for the export of the human drug Revia™ (naltrexone HCl) 50 mg film-coated tablets to Germany.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: James E. Hamilton, Center for Drug Evaluation and Research (HFD-310), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20857, 301-594-3150.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Dupont Merck, Dupont Merck Plaza, Maple Run, Centre Rd., Wilmington, DE

19805, has filed an application requesting approval for the export of the human drug Revia™ (naltrexone HCl) 50 mg film-coated tablets to Germany. The firm holds an approved new drug application for an uncoated tablet, however, this application is for a new film-coated tablet formulation. This product is used as an adjunctive treatment of opioid dependence in detoxified, formerly opioid dependent individuals, and in a proposed indication as an adjunctive treatment for individuals with alcohol dependence undergoing psychosocial treatment programs. The application was received and filed in the Center for Drug Evaluation and Research on April 17, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 30, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: May 4, 1995.

Gayle R. Dolecek,

Acting Director, Office of Compliance, Center for Drug Evaluation and Research.

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BILLING CODE 4160-01-F

National Institutes of Health

National Institute of Dental Research; Notice of Meeting of NIDR Board of Scientific Counselors

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental Research (NIDR), on June 7-9, 1995, in the Natcher Building, Conference Room A, National Institutes of Health, Bethesda, Maryland. The meeting will be open to the public from 8:55 a.m. to recess on June 8 and from