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 Angelini Pharmaceuticals, Inc., 70 Grand Ave., River Edge, NJ 07661, has filed an application requesting approval for the export of the human drug Remydrial® two component system containing Dapiprazole Hydrochloride 50 mg in 260 mg Lyophilized powder and solvent containing 1.0 mg Benzalkonium Chloride in 10 mL bottle to Germany. The firm currently holds an approved new drug application for this product, however, this preparation contains modifications which consists of a formulation change in the solvent for isotonicity, a change in the package size and design for ease of use, and a change in the manufacturer. This product is used for the reversal of medicine-induced pupil dilation. The application was received and filed in the Center for Drug Evaluation and Research on November 22, 1994, 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 February 21, 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: January 31, 1995.

Kathy P. Miracco,

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

[FR Doc. 95–3440 Filed 2–9–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0031]

Drug Export; Valacyclovir Hydrochloride Bulk Drug Substance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Burroughs Wellcome Co. has filed an application requesting conditional approval for the export of the bulk drug substance valacyclovir hydrochloride to the United Kingdom.

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, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2073.

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 Burroughs Wellcome Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709, has filed an application requesting conditional approval for the export of the bulk drug substance valacyclovir hydrochloride to the United Kingdom. The product is indicated for the treatment of herpes zoster (shingles). The application was received and filed in the Center for Drug Evaluation and Research on October 13, 1994, 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 February 21, 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: January 31, 1995.

Kathy P. Miracco,

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

[FR Doc. 95–3442 Filed 2–9–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0032]

Drug Export; Visipaque™ (Iodixanol) Injection 270 Milligrams Iodixanol/Milliliter (mg I/mL) and 320 mg I/mL Supplied in 50 mL Vial, 100 mL, 150 mL, and 200 mL Bottle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Nycomed, Inc., has filed an application requesting approval for the export of the human drug Visipaque™ (iodixanol) Injection 270 milligrams iodixanol/milliliter (mg I/mL) and 320 mg I/mL supplied in 50 mL vial, 100 mL, 150 mL, and 200 mL bottle to Canada.

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, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2073.

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 Nycomed, Inc., 1250 South Collegeville Rd., P.O. Box 5000, Collegeville, PA 19426–0900, has filed an application requesting approval for the export of the human drug Visipaque™ (iodixanol) Injection 270 mg I/mL and 320 mg I/mL supplied in 50 mL vial, 100 mL, 150 mL, and 200 mL bottle to Canada. The product is used in angiocardiography (left ventriculography, aortic root injections, and selective coronary arteriography) and can be used in the diagnosis of coronary artery disease as well as evaluation of the function of the chambers of the heart and heart valves. The application was received and filed in the Center for Drug Evaluation and Research on December 28, 1994, 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 February 21, 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: January 31, 1995.

Kathy P. Mirracco,

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

[FR Doc. 95–3443 Filed 2–9–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 1995 Funding Opportunities for Grants From the Center for Mental Health Services

AGENCY: Center for Mental Health Services, Substance Abuse and Mental Health Services Administration (SAMHSA), HHS

ACTION: Notice of funding availability.

SUMMARY: The Center for Mental Health Services (CMHS), SAMHSA, announces that FY 1995 funds are available for grants for the following activities. These activities are discussed in more detail under Section 4 of this notice.

Activity	Application deadline	Estimated funds available	Estimated number of awards	Project period (years)
AIDS Provider Educ	05/10/95	$980,000	5–6	3
Innovative Child Services	05/10/95	$2.6 million	6–8	3
Consumer/Family Networks	05/10/95	$750,000–1.2 million	5–8	3
Consumer TA Center(s)	05/10/95	$350,000–700,000	1–2	3

The actual amount available for awards and their allocation may vary, depending on unanticipated program requirements and the volume and quality of applications. Awards are made for grant periods which generally run from 1 up to 3 years in duration. FY 1995 funds for mental health services and demonstration programs are appropriated by the Congress under Public Law 103–333. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement applications were published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The Center's mental health services and demonstration activities address issues related to Healthy People 2000 objectives: to promote the physical, social, psychological and economic well-being of adults with mental disorders and children and adolescents with or at risk for a serious emotional, behavioral, or mental disorder.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0) or Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (Telephone: (202) 783–3238).

GENERAL INSTRUCTIONS: Applicants for grants must use application form PHS 5161–1 (Rev. 7/92; OMB No. 0937–0189). The Application Kit contains the PHS 5161–1, Standard Form 424 (Face Page) and *complete instructions* for preparing and submitting applications. The Kit may be obtained from the contact person identified for each activity covered by this notice (see Section 4).

When requesting an Application Kit, the applicant must specify the particular activity(ies) for which detailed information is desired. This is to ensure receipt of all necessary forms and information, including any specific program review and award criteria.

APPLICATION SUBMISSION: Applications must be submitted to: Center for Mental Health Services Programs, Division of Research Grants, NIH, Westwood Building, Room 240, 5333 Westbard Avenue, Bethesda, Maryland 20892.*

APPLICATION DEADLINES: The deadlines for receipt of applications are listed in the table above.

Competing applications must be received by the indicated receipt dates to be accepted for review. An

*If an overnight carrier or express mail is used, the Zip Code is 20816.