catheter sites and other surgical procedures as a film forming skin preparation with persistent broad spectrum antimicrobial activity. The application was received and filed in the Center for Drug Evaluation and Research on October 21, 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. 95–3441 Filed 2–9–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0028]

Drug Export; Colgate Total™ (Sodium Fluoride USP 0.24%, Triclosan 0.30%) Toothpaste

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Colgate-Palmolive Co. has filed an application requesting approval for the export of the human drug Colgate TOTAL™ (sodium fluoride USP 0.24%, triclosan 0.30%) toothpaste 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 Colgate-Palmolive Co., 300 Park Ave., New York, NY 10022–7499, has filed an application requesting approval for the export of the human drug Colgate TOTAL™ (sodium fluoride USP 0.24%, triclosan 0.30%) toothpaste to Canada. This product is indicated for fighting cavities, plaque, tarter, and gingivitis. The application was received and filed in the Center for Drug Evaluation and Research on October 12, 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. 95–3439 Filed 2–9–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0030]

Drug Export; Remydrial® Two Component System Containing Dapiprazole Hydrochloride 50 Milligram (mg) in 260 mg Lyophilized Powder and Solvent Containing 1.0 mg Benzalkonium Chloride

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Angelini Pharmaceuticals, Inc., has filed an application requesting approval for the export of the human drug Remydrial® two component system containing Dapiprazole Hydrochloride 50 milligram (mg) in 260 mg Lyophilized powder and solvent containing 1.0 mg Benzalkonium Chloride in 10 milliliter (mL) bottle 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, 5600 Fishers Lane, Rockville, MD 20857, 301594–2073.

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 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