## Technical Electronic Product Radiation Safety Standards Committee; Recharter

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration announces the rechartering of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC), by the Commissioner of Food and Drugs or designee. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (5 U.S.C. App. 2).

**DATES:** The new charter for this committee will extend to December 24, 1996.

**FOR FURTHER INFORMATION CONTACT:** Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–443–2765.

Dated: February 6, 1995.

**Lireka P. Joseph,**

*Acting Interim Deputy Commissioner for Operations.*

[FR Doc. 95–3437 Filed 2–9–95; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 95F–0021]**

## M & G Ricerche S.p.A.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that M & G Ricerche S.p.A. has filed a petition proposing that the food additive regulations be amended to provide for the safe food contact use of ethylene terephthalate-isophthalate copolymers prepared with pyromellitic dianhydride such that the finished copolymers contain at least 95 weight percent of polymer units derived from ethylene terephthalate.

**DATES:** Written comments on the petitioner's environmental assessment by March 13, 1995.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Richard H. White, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3094.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 5B4444) has been filed by M & G Ricerche S.p.A., c/o 7910 Woodmont Ave., suite 1000, Bethesda, MD 20814. The petition proposes to amend the food additive regulations in § 177.1630 *Polyethylene phthalate polymers* (21 CFR 177.1630) to provide for the safe food contact use of ethylene terephthalate-isophthalate copolymers prepared with pyromellitic dianhydride such that the finished copolymers contain at least 95 weight percent of polymer units derived from ethylene terephthalate.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act, (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before March 13, 1995, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: February 3, 1995.

**Alan M. Rulis,**

*Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.*

[FR Doc. 95–3436 Filed 2–9–95; 8:45 am]

**BILLING CODE 4160–01–F**

**[Docket No. 95N–0029]**

## Drug Export; Chloraprep Frepp® and Chloraprep Sepps® (Chlorhexidine Gluconate 0.5% w/v Isopropyl Alcohol 70% w/v)

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Medi-Flex Hospital Products, Inc., has filed an application requesting approval for The export of the human drug ChloraPrep Frepp® and ChloraPrep Sepps® (chlorhexidine gluconate 0.5% w/v Isopropyl Alcohol 70% w/v) 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 Medi-Flex Hospital Products, Inc., 19 Butterfield Trial Blvd., El Paso, TX 79906, has filed an application requesting approval for the export of the human drug ChloraPrep Frepp® and ChloraPrep Sepps® (chlorhexidine gluconate 0.5% w/v Isopropyl Alcohol 70% w/v) to Canada. This product is indicated for the topical use on peripheral, central venous and arterial

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**