

SUPPLEMENTARY INFORMATION: In the Federal Register of April 20, 1995 (60 FR 19753), FDA announced that a series of Grassroots Regulatory Partnership meetings would be held. Those persons interested in attending this meeting should FAX their comments and registration by Tuesday, April 22, 1996, including name, firm/organization name, address, and telephone number to 404-347-1912. There is no registration fee for this meeting, but advance registration is required. Space is limited and all interested parties are encouraged to register early. The goal of this meeting is to "listen" to concerns and ideas, and to identify next-steps for the agency.

Dated: April 15, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-10023 Filed 4-23-96; 8:45 am]

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[Docket No. 84F-0314]

Coconut Products Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 4A3824) proposing that the food additives regulations be amended to provide for the safe use of polysorbate 60 as an emulsifier to be used in the preparation of coconut milk drink.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3071.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of October 9, 1984 (49 FR 39615), FDA announced that a food additive petition (FAP 4A3824) had been filed by the Coconut Products Corp., 779 Kii St., Honolulu, HI 96825, proposing that § 172.836 *Polysorbate 60* (21 CFR 172.836) be amended to provide for the safe use of polysorbate 60 as an emulsifier in the preparation of coconut milk drink. Coconut Products Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: April 4, 1996.

George H. Pauli,

Acting Director, Office of Pre-market
Approval, Center for Food Safety and Applied
Nutrition.

[FR Doc. 96-10024 Filed 4-23-96; 8:45 am]

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[Docket No. 96N-0125]

Drug Export; Benadryl® Injection Steri-Vials® (Diphenhydramine Hydrochloride Injection, USP) 50 Milligram Per Milliliter (mg/mL), 1-mL Vials

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Parke-Davis Pharmaceutical Research has filed an application requesting approval for the export of the human drug Benadryl® Injection Steri-Vials® 50 mg/mL, 1-mL Vials (diphenhydramine hydrochloride) Injection, USP, to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, 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 20855, 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

Parke-Davis Pharmaceutical Research, 2800 Plymouth Rd., Ann Arbor, MI 48105, has filed an application requesting approval for the export of the human drug Benadryl® Injection Steri-Vials® 50 mg/mL, 1-mL Vials (diphenhydramine hydrochloride) Injection, USP, to Canada. The firm has FDA approval to market this product in 1-mL ampoules and a 1-mL syringe. This product is indicated to be used as an antiallergic, antipruritic, antiemetic, and antispasmodic. The application was received and filed in the Center for Drug Evaluation and Research on November 15, 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 6, 1996, 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: April 5, 1996.

Betty L. Jones,

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

[FR Doc. 96-10020 Filed 4-23-96; 8:45 am]

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[Docket No. 90N-0330]

The Kasdenol Corp., et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing three new drug applications (NDA's) held by The Kasdenol Corp.; Lever Brothers Co., Inc.; and United Pharmaceutical Inc. The basis for the withdrawals is that the holders of the applications have repeatedly failed to