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]

BILLING CODE 4160–01–F

[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 has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).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 Premarket Approval, Center for Food Safety and Applied Nutrition.

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

BILLING CODE 4160–01–F

[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]

BILLING CODE 4160–01–F

[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

file required annual reports on these NDA's.

EFFECTIVE DATE: May 24, 1996.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs or antibiotic drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81).

In the Federal Register of July 13, 1990 (55 FR 28829), FDA offered an opportunity for a hearing on a proposal to withdraw approval of five NDA's because the firms had failed to submit the required annual reports for these NDA's.

The agency had two responses to the notice of opportunity for hearing: From Astra Pharmaceutical Products, Inc.; and from The Purdue Frederick Co. Both responses indicated that the sponsors had previously submitted letters requesting voluntary withdrawal of their NDA's (NDA 13–077 and NDA 11–160, respectively). In the Federal Register of March 27, 1996 (61 FR 13506 at 13507), FDA published a notice that withdrew these applications.

The other three firms did not respond to the notice of opportunity for hearing. Failure to file a written notice of participation and request for a hearing as required by 21 CFR 314.200 constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the NDA's listed in the table in this document.

Application no.	Drug	Applicant
NDA 9–394	Kasdenol Mouthwash or Gargle	The Kasdenol Corp., Huntington, NY 11743.
NDA 10–094	Pepsodent Antiseptic Mouthwash	Lever Brothers Co., Inc., 390 Park Ave., New York, NY 10022.
NDA 13–397	Ampar SRC	United Pharmaceutical Inc., 1500 North Wilmut, Tucson, AZ 85712.

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority of 21 CFR 5.82, finds that the holders of the applications listed above have repeatedly failed to submit reports required by § 314.81. Therefore, pursuant to this finding, approval of the NDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective May 24, 1996.

Dated: April 9, 1996.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 96–10022 Filed 4–23–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. May 2, 1996, 8:30 a.m., and May 3, 1996, 9 a.m., National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Parking in the Clinical Center Visitor area is reserved for clinical center patients and their visitors. If you must drive, please use an outlying lot such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clinical Center every 8 minutes during rush hour and every 15 minutes at other times.

Type of meeting and contact person. Open public hearing, May 2, 1996, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5:30 p.m.; open committee discussion, May 3, 1996, 9 a.m. to 4:30 p.m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419–259–6211; or Valerie M. Mealy, Advisors and Consultants Staff (HFD–21), 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Cardiovascular and Renal Drugs Advisory Committee, code 12533. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in cardiovascular and renal disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 19, 1996, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. On May 2, 1996, the committee will discuss: (1) New drug application (NDA) 20–297, Supplement 1, Coreg® (carvedilol), SmithKline Beecham, to be indicated for use in congestive heart failure; and (2) NDA 20–405, Lanoxin® (digoxin)