dismissed on March 3, 1995. During a June 1, 1995, telephone conversation with FDA staff at the Center for Biologics Evaluation and Research (CBER), one of the owners of the firm stated that the firm ceased operations in December 1994. FDA explained that it could move to revoke the license if the firm remained inoperative. FDA requested a written response within 30 days regarding whether the owners intended to reopen the establishment. As of July 24, 1995, none of the owners had contacted FDA regarding the firm's intentions. In addition, messages left by FDA staff on one owner's telephone answering machine were not answered. An FDA investigator, from the Nashville District Office, was permitted to visit the unoccupied facility by the property owner on August 3, 1995. The investigator documented that the office space and two walk-in freezers were empty and that there was no electrical or water service at the facility. The U.S. Postal Service supplied FDA with the firm's forwarding address, and FDA sent a certified letter, dated September 8, 1995, to the firm's responsible head. The certified letter stated that, under 21 CFR 601.5(b), a license may be revoked if the Commissioner finds that after reasonable efforts authorized FDA employees have been unable to gain access to an establishment for the purposes of conducting an inspection, or that the manufacturing of a product has been discontinued to an extent that a meaningful inspection cannot be made. The letter also stated that following repeated attempts to conduct an inspection, FDA had determined that a meaningful inspection could not be made. The letter provided the firm's responsible head notice of FDA's intent to revoke U.S. License No. 1131 and announced FDA's intent to offer an opportunity for a hearing. The responsible head responded by telephone on September 12, 1995, and said that she was no longer employed by Personal Blood Storage of Memphis, Inc. She also sent a copy of a March 3, 1995, letter to CBER in which she had stated that she was no longer the Technical Director or responsible head for Personal Blood Storage of Memphis, Inc. A copy of FDA's letter of intent to revoke U.S. License No. 1131 was also sent to one owner's address in Texas and was returned by the U.S. Postal Service as unclaimed.

Because FDA made reasonable efforts to notify the firm of the proposed revocation and no response was received from the firm, FDA is proceeding pursuant to 21 CFR 12.21(b) and publishing this notice of an opportunity for a hearing on a proposal to revoke the licenses of the above establishment.

FDA has placed copies of the documents relevant to the proposed license revocation on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. These documents include the following: (1) Record of teleconference dated June 1, 1995; (2) letter to FDA from responsible head dated March 3, 1995; (3) Summary of Findings dated August 3, 1995, (Endorsement-Form FDA 481); (4) FDA certified letter to responsible head dated September 8, 1995; (5) copy of information returned from the U.S. Postal Service showing that the copy of FDA certified letter of September 8, 1995, sent to one owner's Texas address, was unclaimed; and (6) record of teleconference dated September 12, 1995. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Personal Blood Storage of Memphis, Inc., may submit a written request for a hearing to the Dockets Management Branch by May 24, 1996, and any data and information justifying a hearing must be submitted by June 24, 1996. Other interested persons may submit comments on the proposed revocation by June 24, 1996. The failure of the licensee to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation.

FDA procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data and information to justify a hearing on a proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must set forth a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses submitted in support of the request for a hearing that there is no genuine and substantial issue of fact for resolution at a hearing, or if a request for a hearing is not made within the requested time, or in the required format or with the required analyses, the Commissioner of Food and Drugs will deny the hearing request, making available the findings and conclusions that justify the denial.

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. The public availability of information in submissions is governed by 21 CFR 10.20(j)(2)(i). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 351 the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, and 371), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of CBER (21 CFR 5.67).

Dated: April 12, 1996.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 96–10025 Filed 4–23–96; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

Grassroots Regulatory Partnership Meeting; Southeast Region, Atlanta District Office; Turkey/Broiler Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of External Affairs, Office of Regulatory Affairs, Office of the Southeast Region, and Center for Veterinary Medicine) is announcing a free public meeting. FDA's Atlanta District Office (Southeast Region) and the Center for Veterinary Medicine will meet with interested persons in the Southeast Region to address specific issues related to the turkey/broiler industry. The agency is holding this meeting to promote the President's initiative for a partnership approach with front-line regulators and the people affected by the work of the agency, and to create local partnerships.

DATES: The public meeting will be held on Tuesday, May 14, 1996, from 8 a.m. to 5 p.m.

ADDRESSES: The public meeting will be held at the Sheraton Inn—Raleigh at Crabtree Valley, 4501 Creedmoor Rd., Raleigh, NC 27812. Attendees requiring overnight accommodations may contact the hotel at 919–787–7111.

FOR FURTHER INFORMATION CONTACT: JoAnn M. Pittman, FDA Atlanta District, 60 Eighth St. NE., Atlanta, GA 30309, 404–347–7355, or FAX 404–347–1912.

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