expand the activities of an existing office of its subsidiary, Citicorp Acceptance Company, Inc., to include the proposed *de novo* activity of the making of loans to individuals and businesses secured by a lien on mobile homes, modular units or related manufactured housing, together with the real property to which such housing is or will be permanently affixed, such property being used as security for the loans. Such activity would be conducted from an office in Atlanta, Georgia serving the entire States of Georgia, North Carolina and South Carolina. Comments on this application must be received not later than May 5, 1983.

B. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Milford, N.V.*, Oranjestad, Netherlands Antilles, and Ballerton Corporation, Ovideo, Spain (investment advisory activities; Florida, Central and South America, the Caribbean Region): To engage, through their subsidiary, Totalbank Corporation of Florida, Miami, Florida, in the furnishing of general economic information and advice, general economic statistical forecasting services, and industry studies. These activities would be conducted from an office in Miami, Florida, serving the State of Florida, Central and South America, and the Caribbean Region. Comments on this application must be received not later than May 3, 1983.

Board of Governors of the Federal Reserve System, April 5, 1983.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 83-9475 Filed 4-11-83; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA regulations (21 CFR Part 14) relating to advisory committees. The following advisory committee meetings are announced:

Data Analysis Systems Subcommittee of the Science Advisory Board

Date, time, and place. May 5 and 6, 9 a.m., Conference Room, Bldg. 13, National Center for Toxicological Research, Jefferson, AR.

Type of meeting and contact person. Open public hearing, May 5, 9 a.m. to 10 a.m.; open committee discussion, May 5, 10 a.m. to 4:30 p.m., May 6, 9 a.m. to 2:30 p.m.; Lawrence W. Fishbein, National Center for Toxicological Research (HFT-30), Food and Drug Administration, Jefferson, AR 72079, 501-541-4528.

General function of the committee. To assist the Director, National Center for Toxicological Research, in establishing and implementing as well as advising on research and quality assurance programs that will assist the supporting agencies in fulfilling their regulatory responsibilities. The Board as a whole or under the subcommittee structure provides extra-agency review in ensuring that research and data analysis programs at the National Center for Toxicological Research are scientifically sound and pertinent to toxicological problems.

Agenda—Open public hearing. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Open committee discussion. The Subcommittee will hear reports and make recommendations on the following agenda items: (1) Overview of Center activities: short-, intermediate-, and long-term projects; (2) pathology overview; (3) biometry—methods development, extrapolation, and experimental design; (4) Office of Scientific Intelligence Report; and (5) toxicological data management systems.

Radiopharmaceutical Drugs Advisory Committee

Date, time, and place. May 6, 9 a.m., Conference Rm. D, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, 9 a.m. to 11 a.m.; open public hearing, 11 a.m. to 12 m.; open committee discussion, 1 p.m. to 5 p.m.; Neil Abel, National Center for Drugs and Biologics (HFN-150) Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4260.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the practice of nuclear medicine.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Open committee discussion. The committee will discuss the status of the investigational new drug regulations rewrite; orphan drug development with regard to the Hatch Amendment; status of limulus amebocyte lysate testing for radiopharmaceuticals; petitions concerning unapproved uses for approved drugs; recommendations for changes in the radiopharmaceutical drugs research committee regulations; preservatives in Technetium Tc 99m labeled kits; expiration time for Technetium Tc 99m Pertechnetate; and international system of units for radiopharmaceuticals.

Arthritis Advisory Committee

Date, time, and place. May 12 and 13, 9 a.m., Conference Rm. E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, May 12, 9 a.m. to 10 a.m.; open committee discussion, May 12, 10 a.m. to 4 p.m., May 13, 9 a.m. to 4 p.m.; Dotti Moore, National Center for Drugs and Biologics (HFN-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5197.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in arthritic conditions.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Open committee discussion. The committee will discuss statistical guidelines for nonsteroidal anti-inflammatory drugs; comparative efficacy claims for nonsteroidal anti-inflammatory drugs; and adverse reactions among nonsteroidal anti-inflammatory drugs.

Endocrinologic and Metabolic Drugs Advisory Committee

Date, time, and place. May 19 and 20, 9 a.m., Conference Rms. G and H, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and executive secretary. Open public hearing, May 19, 9 a.m. to 10 a.m.; open committee

discussion, May 19, 10 a.m. to 5 p.m., May 20, 9 a.m. to 5 p.m.; A. T. Gregoire, National Center for Drugs and Biologics (HFN–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1869.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drug products for use in treating endocrine and metabolic disorders.

Agenda—Open public hearing. Interested persons who want to present data, information, or views, orally or in writing, on issues pending before the committee should communicate with the committee executive secretary.

Open committee discussion. The committee will discuss: (1) Use of DDAVP (NDA 17–922) in mild hempophilia A and von Willebrands Disease and; (2) Winstrol (NDA 12–885) for osteoporosis and aplastic anemia.

Gastrointestinal Drugs Advisory Committee

Date, time, and place. May 20, 9 a.m., Auditorium, Lister Hill Center, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. Open public hearing, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 5 p.m.; Joan C. Standaert, National Center for Drugs and Biologics (HFN–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4730.

General function of the committee. The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational prescription drug products for use in gastrointestinal disorders.

Agenda—Open public hearing. Any interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Open committee discussion. The committee will discuss possible labeling changes for Ethrane (enflurane) NDA 17–087, Ohio Medical, based on available data with respect to effects on the liver.

Immunology Device Section of the Immunology and Microbiology Devices Panel

Date, time, and place. May 23, 9 a.m., Rm. 703A–727A, 200 Independence Ave. SW., Washington, DC.

Type of meeting and panel section leader. Open public hearing, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 12 m.; open committee discussion, 1 p.m. to 5 p.m.; Srikrishna Vadlamudi, National Center for Devices and Radiological Health (HFK–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of devices and makes recommendations for their regulation.

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 panel section leader before May 6, 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. The committee will discuss a premarket approval application for alpha-fetoprotein reference preparation.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairman determines will facilitate the committee's work.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be requested from the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

Dated: April 6, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-9470 Filed 4-11-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 83F-0087]

Armak Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing that Armak Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of an anionic polyurethane as a component of paper and paperboard in contact with aqueous and fatty foods.

FOR FURTHER INFORMATION CONTACT: John L. Herrman, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (see 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 8B3370) has been filed by Armak Co., 300 S. Wacker Dr., Chicago, IL 60606, proposing that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended to provide for the safe use of an anionic polyurethane porduced by reacting the preliminary adduct formed from the reaction of glyceryl monostearate and toluene diisocyanate with a mixture of *N*-methyldiethanolamine and dimethylolpropionic acid.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 1, 1983.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 83-9467 Filed 4-11-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 75N-0184; DESI 597]

Bentyl Syrup With Phenobarbital; Drug Efficacy Study Implementation; Revocation of Temporary Exemption; Proposal To Withdraw Approval of New Drug Application; Opportunity for Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice revokes the temporary exemption that allowed Bentyl Syrup with Phenobarbital to remain on the market beyond the time limit established for the implementation of the Drug Efficacy Study. This notice also reclassifies the drug to lacking substantial evidence of effectiveness, proposes to withdraw approval of the new drug application, and offers an oportunity for hearing on the proposal.

DATES: The revocation of the temporary exemption is effective April 12, 1983; written notice of appearance and request for hearing must be submitted by May 12, 1983; material to support hearing request must be submitted by June 13, 1983.

ADDRESSES: Communications in response to this notice should be identified with Docket No. 75N–0184 and DESI 597 and directed to the appropriate office named below.

Requests for hearing, supporting data and information, reports of other studies, and other comments: Dockets Management Branch (HFA–305) Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFN–310), National Center for Drugs and Biologics, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Susanne O'Shea, National Center for Drugs and Biologics (HFN–8), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–433–3650.

SUPPLEMENTARY INFORMATION: This notice covers the drug product listed below and any identical, similar, or related product (see 21 CFR 310.6) that is not the subject of an approved new drug application (NDA).

NDA 7–961; Bentyl Syrup with Phenobarbital containing dicyclomine hydrochloride 10 mg/5 mL and phenobarbital 15 mg/5 mL; Merrell-Dow Pharmaceuticals, 110 E. Amity Rd., Cincinnati, OH 45215. (NDA 7–961 also covers Bentyl Syrup containing dicyclomine hydrochloride alone. This product will be the subject of a future **Federal Register** notice.)

In a notice published in the **Federal Register** of July 27, 1972 (37 FR 15026), the Food and Drug Administration (FDA) classified Bentyl Syrup with Phenobarbital as possibly effective in the treatment of the irritable bowel syndrome, neurogenic bowel disturbances, infant colic, and as adjunctive therapy in the treatment of peptic ulcer. In a notice published in the **Federal Register** of November 11, 1975 (40 FR 52644), FDA announced that the product could remain on the market pending completion of clinical trials under an exemption from the time limits established in *American Public Health Ass'n* v. *Veneman*, 349 F. Supp. 1311 (D.D.C. 1972); (see also the **Federal Register** of December 14, 1972 (37 FR 26623)). The 1975 notice established time limits for submitting protocols and allowed manufacturers 18 months to complete their studies. In a notice published in the **Federal Register** of June 20, 1978 (43 FR 26490), the deadline for completion of the studies was extended to September 30, 1978. Because ample time has been provided for conducting trials, the exemption is now revoked.

On September 28, 1978, Merrell submitted a medical rationale and data intended to demonstrate the effectiveness of Bentyl Syrup with Phenobarbital in the irritable bowel syndrome (IBS) and infant colic. The National Center for Drugs and Biologics (NCDB; formerly called the Bureau of Drugs) has completed its review of these data and concludes that they do not constitute substantial evidence of effectiveness. A discussion follows.

1. *Irritable bowel syndrome.* Merrell argues that IBS has two inseparable components: gastrointestinal symptoms, and symptoms of anxiety, depression, or other psychoneurotic disorders. Merrell states that because Bentyl (dicyclomine hydrochloride alone) is effective treatment of gastrointestinal symptoms, and phenobarbital is an effective anti-anxiety agent, Bentyl Syrup with Phenobarbital should be available for those patients who require treatment with both ingredients. Merrell submitted copies of 31 literature references intended to establish that symptoms of anxiety or depression are inseparable for gastrointestinal symptoms and that barbiturates (including phenobarbital) are effective in anxiety. The firm relies on data derived from clinical investigations of Bentyl Tablets to establish its effectiveness in gastrointestinal symptoms. Merrell notes further advantages of combination products, e.g. patient convenience, better patient compliance, and economy.

Merrell seems to suggest by this medical rationale that Bentyl Syrup with Phenobarbital could be indicated, not for treatment of gastrointestinal disease alone, but for treatment of two independent conditions, gastrointestinal disease and anxiety, when the two conditions coexist. However, simply combining a drug effective in treating IBS (assuming that Bentyl is effective in IBS) with an effective anti-anxiety agent does not necessarily result in a combination product that meets the criteria of the combination policy (21 CFR 300.50(a)). The combination policy requires that the components be present in a "dosage * * * (amount, frequency, duration) such that the combination is safe and effective for a significant population requiring such concurrent therapy * * *." Accordingly, to meet the combination policy, Merrell must demonstrate the existence of a patient population needing concomitant treatment of two separate disorders, gastrointestinal disease and anxiety (i.e., a physician seeing such a patient without any gastrointestinal disease but with the same degree of anxiety would prescribe phenobarbital in the amount present in Bentyl Syrup with Phenobarbital). In addition, evidence must be presented that the gastrointestinal disease and anxiety arise and disappear more or less simultaneously so that neither drug is given for a condition that is no longer present. In the absence of evidence that Bentyl Syrup with Phenobarbital meets these criteria, factors such as increased patient compliance and convenience cannot be considered true advantages.

The literature references listed below provide some evidence that IBS and some psychological disorders sometimes occur simultaneously.

However, the psychological disorders discussed were often poorly defined. For