with this requirement. Individuals denied such care have a right to appeal that denial to the Secretary. Respondents: Individuals or households, State or local governments, Non-profit institutions. Number of Respondents: 4,041; Frequency of Response: Occasionally; Estimated Annual Burden: 1,704,142 hours.

2. Common Reporting Requirements for Urban Indian Health Programs—0915-0096—Congress has mandated that standard reporting requirements be established for 35 urban Indian health programs. Data collected are used for contract monitoring purposes, reports to Congress, establishing indicators, etc. Respondents: Non-profit institutions. Number of Respondents: 35; Frequency of Response: Semi-annually; Estimated Annual Burden: 1,120 hours.

3. Health Education Assistance Loan (HEAL) Program—Forms—0915-0034—The status form permits lenders to grant authorized periods of deferment. The Manifest provides information about HEAL loan activity. The transfer identifies reassigned loans. Lenders use the application to apply for a contract of insurance. Respondents: Individuals or households, Businesses or other for-profit, Non-profit institutions. Number of Respondents: 3,349; Frequency of Response: Occasionally; Estimated Annual Burden: 2,674 hours.

OMB Desk Officer: Shanna Koss-McCallum

As mentioned above, copies of the information collection clearance packages can be obtained by calling the Reports Clearance Officer, on one of the following numbers:

PHS: 202-245-2100
HCFA: 301-594-8650
SSA: 301-594-5706
HDS: 202-472-4415
FSA: 202-245-0652

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address:

OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, DC 20503, ATTN: (Name of OMB Desk Officer)

Date: August 10, 1987.

James F. Trickett,

Deputy Assistant Secretary, Administrative and Management Services.

[FR Doc. 87-18704 Filed 8-14-87; 8:45 am]

BILLING CODE 4150-04-M

Food and Drug Administration

Advisory Committees; 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 summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

Meetings: The following advisory committee meetings are announced:

Blood Products Advisory Committee

Date, time and place. September 17 and 18, 1987, 9 a.m., Rm. 121, Office of Biologics Research and Review, 8800 Rockville Pike, Bethesda, Maryland.

Type of meeting and contact person. Open public hearing, September 17, 1987, 9 a.m. to 10 a.m.; unless public participation does not last that long; open committee discussion, 10 a.m. to 11 a.m.; closed presentation of data, 11 a.m. to 4:30 p.m.; closed committee discussion, September 18, 1987, 8:30 a.m. to 1 p.m., Clay Sisk, Center for Drugs and Biologics (HFN-32), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

General function of the committee. The committee reviews and evaluates available data on the safety, effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons requesting to present data, information, or views, orally or in writing, on issues pending before the committee should communicate with the committee contact person.

Open committee discussion. The committee will discuss methods for reevaluation of persons who are currently defferred from donating blood because of reactive hepatitis B surface antigen (HBsAg) tests, but which upon further more specific testing again may be acceptable as donors.

Closed presentation of data. The committee will discuss trade secret and/or confidential commercial information relevant to pending investigational new biological products and a license application for a designated orphan drug, alpha-1-proteinase inhibitor for use in replacement therapy in the alpha-1-proteinase congenital deficient state. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Vaccines and Related Products Advisory Committee

Date, time, and place. September 21, 1987, 8:30 a.m., and September 22, 1987, 9 a.m., Building 29, Rm. 121, 8800 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. Open public hearing, September 21, 1987, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; closed committee deliberations, 9:30 a.m. to 5 p.m.; closed committee deliberations, September 22, 1987, 9 a.m. to 2:30 p.m.; Jack Gertzog, Center for Drugs and Biologics (HFN-31), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of vaccines and related biological products intended for use in the diagnosis, prevention, or treatment of human diseases. The committee also reviews and evaluates the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

Agenda—Open public hearing. Interested persons requesting to present data, information, or views, orally or in writing, on issues pending before the committee should communicate with the committee contact person.

Closed committee deliberations. The committee will review trade secret and/or confidential commercial information relevant to pending license applications and status of IND's in the Office of Biologics Research and Review. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Clinical Chemistry and Clinical Toxicology Devices Panel

Date, time and place. September 21 and 22, 1987, 9 a.m., Rm. 337A-339A, Hubert H. Humphrey Bldg., 200 Independence Ave., SW., Washington, DC.

Type of meeting and contact person. Open public hearing, September 21, 1987, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 12 m.; open presentation of data, 1 p.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 4 p.m.; open committee discussion, 4 p.m. to 5 p.m.; open public hearing, September 22, 1987, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. 12 m.; open presentation of data, 1 p.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 4 p.m.; open committee discussion, 4 p.m. to 5 p.m.; Kaiser Aziz, Center for Devices and Radiological Health (HFZ-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 person may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make oral presentations should notify the contact person before September 1, 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 two premarket approval applications: (1) Histochemical assay designed to detect estrogen binding cancer cells in human breast cancer, and (2) radioreceptor assay designed to measure estrogen receptors in tissue cytosol in the management of breast cancer patients.

Closed committee deliberations. The committee will discuss trade secret and/or confidential commercial information relevant to the premarket approval applications for the above histochemical and radioreceptor assays. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Circulatory System Devices Panel

Date, time, and place. September 25, 1987, 8:30 a.m., Rm. 703A, Hubert H. Humphrey Bldg., 200 Independence Avenue SW., Washington, DC.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9 a.m.; open committee discussion, 9 a.m. to 2 p.m.; closed committee deliberations, 2 p.m. to 4 p.m.; Keith Lusted, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301–427–7373.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of medical devices currently in use 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 contact person before September 11, 1987, 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 premarket approval applications (PMA's) for two percutaneous transluminal coronary angioplasty (PTCA) catheters.

Closed committee deliberations. The committee will discuss trade secret and/or confidential commercial information regarding the PMA's listed above. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate 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 chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (Subpart C of 21 CFR Part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR Part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

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 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 chairperson'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.

Details on the agenda, questions to be addressed by the committee, and a current list of committee members are available from the contact person before and after the meeting. Transcripts of the open portion of the meeting will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, Rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting will be available from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA), as amended by the Government in the Sunshine Act (Pub. L. 94–409), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may

be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice 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's regulations (21 CFR Part 14) on advisory committees.

Dated: August 10, 1987.

John A. Norris,

Acting Commissioner of Food and Drugs.

[FR Doc. 87–18669 Filed 8–14–87; 8:45am]

BILLING CODE 4160–01–M

[Docket No. 87F–0239]

Filing of Food Additive Petition; Hercules, Inc.

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Hercules, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting *N*-methyl-bis(3-aminopropyl)amine with oxalic acid and urea or dimethylglutarate to form a basic polyamide and further reacting the polyamide with epichlorohydrin. The polyamide-epichlorohydrin resins will be used to impart wet strength to paper and paperboard in contact with aqueous and fatty foods.

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 7B3986) has been filed by Hercules, Inc., Hercules Plaza, Wilmington, DE 19894, 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 polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting *N*-methyl-bis(3-aminopropyl)-amine with oxalic acid and urea or dimethylglutarate to form a basic polyamide and further reacting the polyamide with epichlorohydrin. The polyamide-epichlorohydrin resins will be used to impart wet strength to paper and paperboard in contact with aqueous and fatty foods.

The potential environmental impact of this action is being reviewed. If 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: August 10, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87–18668 Filed 8–14–87; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 87M–0236]

Paco Pharmaceutical Services, Inc.; Premarket Approval of Charter Labs Preserved Saline Solution

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Paco Pharmaceutical Services, Inc., Lakewood, NJ, for premarket approval, under the Medical Device Amendments of 1976, of the Charter Labs Preserved Saline Solution. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the application.

DATE: Petitions for administrative review by September 16, 1987.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301–427–7940.

SUPPLEMENTARY INFORMATION: On April 14, 1987, Paco Pharmaceutical Services, Inc., Lakewood, NJ 08701, submitted to CDRH an application for premarket approval of the Charter Labs Saline Solution for use in the rinsing, heat disinfection, and storage of soft (hydrophilic) contact lenses.

On May 29, 1987, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On June 25, 1987, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ–460), address above.

The labeling of the Charter Labs Preserved Saline Solution states that the solution is indicated for use in the rinsing, heat disinfection, and storage of soft (hydrophilic) contact lenses. Manufacturers of soft (hydrophilic) contact lenses that have been approved for marketing are advised that whenever CDRH publishes a notice in the **Federal Register** of the approval of a new solution for use with an approved soft contact lens, the manufacturer of each lens shall correct its labeling to refer to the new solution at the next printing or

at such other time as CDRH prescribes by letter to the applicant.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before September 16, 1987, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554–555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: August 7, 1987.

James S. Benson,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 87–18670 Filed 8–14–87; 8:45 am]

BILLING CODE 4160–01–M

Consumer Participation; Open Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following consumer exchange meetings:

Dallas District Office, chaired by Gerald F. Vince, District Director. The topics to be discussed are food safety and imports.

Date: Thursday, August 27, 1987, 10 a.m. to 11:30 a.m.

Address: 727 East Durango Blvd., Rm. B–406, San Antonio, TX.

For Further Information Contact: Juan A. Tijerina, Consumer Affairs Officer, Food and Drug Administration, 727 East Durango Boulevard, Room B–406, San Antonio, TX 78206, 512–229–6737.

Detroit District Office, chaired by Alan L. Hoeting, District Director. The topics to be discussed are health claims on food labels and treatment use of investigational new drugs.

Date: Monday, August 31, 1987, 9 a.m. to 10:15 a.m.

Address: Indiana Convention Center, 100 South Capitol Ave., Rm. 138, Indianapolis, IN 46204.

For Further Information Contact: L. M. Goossens, Consumer Affairs Officer, Food and Drug Administration, 575 North Pennsylvania Street, Room 693, Indianapolis, IN 46204, 317–269–6500.

Detroit District Office, chaired by Alan L. Hoeting, District Director. The topic to be discussed is health claims on food labels.

Date: Tuesday, September 15, 1987, 10 a.m.

Address: George Potter Larrick Bldg., Conference Room, 1560 East Jefferson St., Detroit, MI 48207.

For Further Information Contact: Evelyn DeNike, Consumer Affairs Officer, Food and Drug Administration, 1560 East Jefferson Street, Detroit, MI 48207, 313–226–6260.

SUPPLEMENTARY INFORMATION: The purpose of these meetings is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's District Offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: August 7, 1987.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–18671 Filed 8–14–87; 8:45 am]

BILLING CODE 4160–01–M

Health Care Financing Administration

[HSQ–148–GNC]

Medicare Program; Selected Performance Information on Hospitals Providing Care to Medicare Beneficiaries

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice announces our intent to release, through a HCFA publication, selected statistical information on the performance of hospitals participating in the Medicare program. We believe that information about hospitals' overall post-admission mortality rates and specific mortality rates for certain medical conditions will be a valuable tool for Peer Review Organizations (PROs) for focusing on potential quality of care problems, for hospitals in focusing their efforts on improving the quality of care they provide, and for consumers in making decisions on obtaining health care. This information release is one part of HCFA's continuing initiative to promote quality of care which encompasses a broad range of regulatory, operational, and research efforts.

This notice describes the areas of concentration and summarizes the analytical methodology that we propose to use to produce this information.

DATE: To be considered, comments on this notice must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on September 14, 1987.

ADDRESS: Address comments in writing to: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ–148–GNC, P.O. Box 26676, Baltimore, Maryland 21201.

If you prefer, you may deliver your comments to one of the following locations:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, or,

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Md.

In commenting, please refer to file code HSQ–148–GNC. Comments will be available for public inspection as they are received, beginning approximately 3 weeks after publication of the notice, in Room 309–G of the Departmental Offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (202–245–7890).