Plans, directs and evaluates activities authorized under Title IV of the OAA. Conducts activities for the development of adequate knowledge for improving the circumstances of older people. Develops a knowledge base for policy decisions and program development and coordination through support of a wide range of research, demonstration, and training activities.

Prepares the planning documents for, and coordinates the development of, the annual discretionary funds program announcement. Provides technical input for Congressional and budget presentations related to the research and demonstration program. Evaluates research, demonstration and training grant and contract proposals; and recommends approval/disapproval, monitors progress, gives technical guidance to and evaluates the performance of grantees and contractors. Analyzes and interprets project results and recommends technical applications. Promotes coordination of research and demonstrations with other national, field and local programs related to aging.

Within overall AoA strategy and long range plans, conducts continuing studies and periodic reviews of personnel needs and resources in the field of aging. Plans and assesses AoA's activities to ensure trained staff for programs serving older Americans. Develops and monitors a national plan for increasing these resources, and prepares reports thereon for AoA, the Federal Council on the Aging, the Secretary, the President and Congress.

Administers a program through grants and contracts for developing curricula and providing training related to preparation for professional, teaching, research, and paraprofessional careers in the field of aging. Makes grants for planning, developing, and operating multi-disciplinary centers of gerontology designed to serve the purposes set forth under Title IV of the OAA, including the monitoring of such grants on a continuing basis.

Develops standards, optional models, and ''best practice'' suggestions on services to the elderly for use by the Regional Offices, and State and Area Agencies on Aging. Develops technical assistance material and in-service training curricula concerning these standards, models, and best practice suggestions.

Provides technical input on research, demonstration and training programs to the AoA planning and policy development activities, legislative activities and the annual budget development cycle. Participates in Departmental and inter-departmental activities which concern health and social services; reviews and comments on Departmental regulations and policies regarding health programs and institutional and non-institutional long term care services.

Manages a program for the collection, analysis, and dissemination of information related to the needs and problems of older persons. Develops and coordinates initiatives with other Federal agencies, national aging organizations and universities to fill gaps in information in the field of aging.

Reviews all products from AoA, the OAA network, and other sources of information on aging to identify new findings which will be useful to older people and professionals operating in the field of aging. Determines the relative utility of each product, its potential users, and the most effective way to disseminate information to users.

Dated: December 12, 1995.

Fernando M. Torres-Gil,

Assistant Secretary for Aging.

[FR Doc. 95–30732 Filed 12–18–95; 8:45 am]

BILLING CODE 4130–01–P

Agency for Health Care Policy and Research

Meeting of the National Advisory Council for Health Care Policy, Research, and Evaluation

AGENCY: Agency for Health Care Policy and Research, HHS.

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the National Advisory Council for Health Care Policy, Research, and Evaluation.

DATES: The meeting will be open to the public on Friday, January 26, from 8:30 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Madison Hotel, 1177 5th Street, NW., Washington, DC 2005.

FOR FURTHER INFORMATION CONTACT: Deborah L. Queenan, Executive Secretary of the Advisory Council at the Agency for Health Care Policy and Research, 2101 East Jefferson Street, Suite 603, Rockville, Maryland 20852, (301) 594–1459.

In addition, if sign language interpretation or other reasonable accommodation for a disability is needed, please contact Linda Reeves, the Assistant Administrator for Equal Opportunity, AHCPR, or (301) 594–6665 no later than January 19, 1996.

SUPPLEMENTARY INFORMATION:

I. Purpose

Section 921 of the Public Health Service Act (42 U.S.C. 299c) establishes the National Advisory Council for Health Care Policy, Research, and Evaluation. The Council provides advice to the Secretary and the Administrator, Agency for Health Care Policy and Research (AHCPR), on matters related to AHCPR activities to enhance the quality, appropriations, and effectiveness of health care services and access to such services through scientific research and the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services.

The Council is composed of public members appointed by the Secretary. These members are: Robert A. Berenson, M.D.; F. Marian Bishop, Ph.D.; Linda Burnes Bolton, Dr. P.H.; John W. Danaher, M.D.; Helen Darling, M.A.; Nancy J. Kaufman, M.S.; William S. Kiser, M.D.; Robert M. Krughoff; Risa J. Lavizzo-Mourey, M.D.; W. David Leak, M.D.; Harold S. Luft, Ph.D.; Barbara J. McNeil, M.D.; Walter J. McNerney, M.H.A.; Edward B. Perrin, Ph.D.; Louis F. Rossiter, Ph.D.; Albert L. Sui, M.D.; and Ellen B. White. M.B.A.

There also are Federal ex-officio members. These members are: Administrator, Substance Abuse and Mental Health Services Administration; Director, National Institutes of Health; Director, Centers for Disease Control and Prevention; Administrator, Health Care Financing Administration; Commissioner, Food and Drug Administration; Assistant Secretary of Defense (Health Affairs); and Chief Medical Director, Department of Veterans Affairs.

II. Agenda

On Friday, January 26, 1996, the meeting will begin at 8:30 a.m. with the call to order by the Council Chairman. The Administrator, AHCPR, will update the status of current Agency issues and program initiatives. Council will then discuss the issues of health services research work force and education, public/private sector collaboration, and the large grant review process. The meeting will adjourn at 5:00 p.m.

Agenda items are subject to change as priorities dictate.

Dated: December 7, 1995.

Clifton R. Gaus,

Administrator.

[FR Doc. 95–30742 Filed 12–18–95; 8:45 am]

BILLING CODE 4160–90–M

Food and Drug Administration

[Docket No. 95M–0397]

Progressive Angioplasty Systems, Inc.; Premarket Approval of the PAS Lacrosse™ PTCA Catheter

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Progressive Angioplasty Systems, Inc., Menlo Park, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the PAS LaCrosse™ PTCA Catheter. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 27, 1995, of the approval of the application.

DATES: Petitions for administrative review by January 18, 1996.

ADDRESSES: 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, 12420 Parklawn Dr., rm . 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Veronica Price, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On April 4, 1994, Progressive Angioplasty Systems, Inc., Menlo Park, CA 94025–1516, submitted to CDRH an application for premarket approval of the PAS LaCrosse™ PTCA Catheter. The device is a percutaneous transluminal coronary angioplasty (PTCA) dilatation catheter and it is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicated information previously reviewed by this panel. On September 27, 1995, 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.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, 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 the 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 January 18, 1996, 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) (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: December 4, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 95–30743 Filed 12–18–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95M–0393]

Bioetica, Inc.; Premarket Approval of HEMOSTAGENE® Absorbable Collagen Hemostatic Sponge

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Bioetica, Inc., Westbrook, ME, on behalf of Coletica, S. A., Lyon, France, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of HEMOSTAGENE® Absorbable Collagen Hemostatic Sponge. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of August 15, 1995, of the approval of the application.

DATES: Petitions for administrative review by January 18, 1996.

ADDRESSES: 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Frances M. Curtis, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION: On August 30, 1993, the U.S. representative, Bioetica, Inc., Westbrook, ME 04092, on behalf of Coletica, S. A., Lyon, France, submitted to CDRH an application for premarket approval of HEMOSTAGENE® Absorbable Collagen Hemostatic Sponge. The device is an absorbable hemostatic agent and is indicated for use in surgical procedures (other than in neurosurgical, ophthalmic, and urological) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the General and Plastic Surgery Devices Panel of the