1. Glacier Bancorp, Inc., Kalispell, Montana; to acquire 100 percent of the voting shares of Big Sky Western Bank, Big Sky, Montana.

2. First National Bank At St. James ESOP, St. James, Minnesota; to acquire an additional 15.67 percent, for a total of 39.85 percent, of the voting shares of First National Agency At St. James, St. James, Minnesota, and thereby indirectly acquire First National Bank At St. James, St. James, Minnesota.

Board of Governors of the Federal Reserve System, October 28, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–29326 Filed 11–2–98; 8:45 am]

BILLING CODE 6210–01–M

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 17, 1998.

A. Federal Reserve Bank of New York (Betsy Buttrill White, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001:

1. HSBC Holdings PLC, London, England; HSBC Finance (Netherlands) Limited, London, England; HSBC Holdings BV, Amsterdam, The Netherlands, and Hongkong Bank of Canada, Vancouver, British Columbia, Canada; to acquire Gordon Capital Corporation, Toronto, Ontario, Canada, Gordon Capital Holdings Inc., and Gordon Capital, Inc., both of New York, New York, and thereby engage in agency brokerage and private placement activities, pursuant to § 225.28(b)(7) of Regulation Y. These activities will be conducted worldwide.

B. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Central Louisiana Capital Corporation, Vidalia, Louisiana; to acquire Community Credit Centers, Inc., Natchez, Mississippi and Monroe, Louisiana, and thereby engage in consumer finance, pursuant to § 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, October 28, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–29325 Filed 11–2–98; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Nominations of Topics for Research on Therapeutics

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

ACTION: Notice.

SUMMARY: The Agency for Health Care Policy and Research (AHCPR) invites nominations of topics of study and ideas for implementation of a new program, Centers for Education and Research on Therapeutics, which will be established by AHCPR in conjunction with the Food and Drug Administration (FDA). The program is described in Section 409 of the Food and Drug Modernization Act, quoted below. AHCPR plans to publish during Fiscal Year 1999 a Request for Applications (RFA) for cooperative agreements to establish and operate one or more Centers. Nominated topics selected by AHCPR will be considered in developing the RFA.

Sec. 409. Centers for Education and Research on Therapeutics

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end of part A the following new section:

Sec. 905. Demonstration Program Regarding Centers for Education and Research on Therapeutics

(a) In General.—The Secretary, acting through the Administrator and in consultation with the Commissioner of Food and Drugs, shall establish a demonstration program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in subsection (b).

(b) Required Activities.—The activities referred to in subsection (a) are the following:

(1) The conduct of state-of-the-art clinical and laboratory research for the following purposes:

(A) To increase awareness of—

(i) New uses of drugs, biological products, and devices;

(ii) Ways to improve the effective use of drugs, biological products, and devices; and

(iii) Risks of new uses and risks of combinations of drugs and biological products.

(B) To provide objective clinical information to the following individuals and entities:

(i) Health care practitioners or other providers of health care goods or services;

(ii) Pharmacy benefit managers;

(iii) Health maintenance organizations or other managed health care organizations;

(iv) Health care insurers or governmental agencies; and

(v) Consumers.

(C) To improve the quality of health care while reducing the cost of health care through—

(i) The appropriate use of drugs, biological products, or devices; and

(ii) The prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

(2) The conduct of research on the comparative effectiveness and safety of drugs, biological products, and devices.

(3) Such other activities as the Secretary determines to be appropriate, except that the grant may not be expended to assist the Secretary in the review of new drugs.

DATES: To be considered for Fiscal Year 1999, nominations of topics and ideas for implementation for CERTS, in accordance with the criteria set out below, should be submitted by December 18, 1998. Nominations after that date will be accepted on an ongoing basis for consideration in future studies.

ADDRESSES: Nominations of topics and ideas for implementation should be sent to: Center for Outcomes and Effectiveness Research, AHCPR; ATTENTION: Joanne Book; 6010 Executive Boulevard; Suite 300; Rockville, Maryland 20852 or e-mail at jbook@ahcpr.gov. All responses will be available for public inspection at AHCPR's Information Resource Center (IRC) public reading room between the hours of 8:30 a.m. and 5 p.m. on regular business days at 2101 East Jefferson Street, Suite 500, Rockville, MD 20852.

Arrangements for reviewing the submissions may be made by calling 301 594–1360. Responses may also be accessed after December 1, 1998, through AHCPR's Electronic FOIA Reading Room on AHCPR's Website *(www.ahcpr.gov).*

FOR FURTHER INFORMATION CONTACT: Lynn Bosco, M.D., M.P.H., Medical Officer, COER, AHCPR, at the above address. (Phone 301 594–1485; e-mail lbosco@ahcpr.gov)

SUPPLEMENTARY INFORMATION: The Food and Drug Administration Modernization Act of 1997 (Pub.L. 105–115) added a new section 905 to Title IX of the PHS Act (codified at 42 U.S.C. 299a–3). Section 905 requires AHCPR, in consultation with FDA, to set up a demonstration program for grants to establish Centers for Education and Research on Therapeutics to conduct research for the purposes set out above. AHCPR plans to publish, during Fiscal Year 1999, an RFA for cooperative agreements to establish and operate one or more Centers.

In FY 1999 there will be up to $2 million available to fund one or more centers. Recognizing the broad mission outlined in the legislation, AHCPR is requesting comments on:

- How the centers should be organized;
- The appropriateness of AHCPR or these centers seeking additional funding partners to increase the resources available for research;
- Initial area(s) of emphasis, drawing from the list outlined in the statute (reprinted above);
- High-priority research topics within the suggested initial area(s) of emphasis;
- Whether the Agency should include a list of specific research topics in the RFA to which applicants would respond or whether the RFA should focus primarily on the infrastructure and capacity of applicants and identify specific research issues to be addressed following selection of the centers; as well as
- Other issues that respondents believe need to be taken into account by the Agency in the implementation of this legislation.

General Considerations in Responding to these Questions.

Organization of the Centers. Are there existing frameworks, such as the NIH project or center grants (e.g. the Cancer Centers or Multipurpose Arthritis Centers), that could serve as a model project for the organization of these Centers?

Topic Selection. In developing topics and suggestions for how Centers might be organized, the roles of AHCPR and FDA, as defined below, should be considered. The FDA regulations most currently marketed drugs, biologics and medical devices. In order for marketing to occur, pre-marketing studies must be completed, with final approval for marketing contingent on manufacturers providing FDA evidence of safety and efficacy for a single indication through adequate and well-controlled studies. (The majority of devices receive clearance rather than approval after the manufacturer provides evidence that the product is substantially equivalent to a device that is already on the market).

Current regulations do not require information on how these products compare with the array of other existing therapies available, or use in the every day clinical settings. FDA regulation continues during the post-approval phase, through post marketing safety monitoring and through regulation of advertising.

The AHCPR activities related to therapeutics begin after product approval. The AHCPR supports research on the relative effectiveness, appropriateness, and cost effectiveness of various strategies for the prevention, diagnosis, treatment, and management of clinical conditions. Activities have included development and administration of a program to study patient outcomes, development of clinical guidelines and evidence based practice centers, and support of the development of quality measures.

The appropriate use of medical therapies, such as drugs, biologics and devices is critical to effective, high quality, affordable health care. Understanding which agents work; for which patients; and at what cost and risk; can inform programs in managing the selection, utilization, and cost of therapies and services within a changing health care environment. The Centers for Education and Research on Therapeutics will seek to make more information available after marketing to fill the gap between the research required for approval and the need for information to assist clinicians in the everyday use of products.

Selection Criteria

FDA's needs related to the necessity for going beyond the current voluntary reporting system to obtain needed safety and effectiveness information for providing guidance to practitioners on appropriate product use. The current post-marketing surveillance system provides only a fraction of the actual number of problems associated with product use, with only limited information available on the numbers of patients exposed to products. Little information is available on the interaction between the provider, product and patient. This is particularly important when a high degree of skill is required of either the provider or patient to use a product, thus making it difficult to determine whether problems relate to provider or patient error, product defect or an adverse event.

Selection criteria for AHCPR sponsored research have been the following: (1) High incidence or prevalence in the general population or in subpopulations, including racial and ethnic minorities, women and children; (2) significance to the Medicare, Medicaid and other Federal health programs; (3) high costs associated with a condition, procedure, treatment, or technology, whether due to the number of people needing care, high unit cost of care, or high indirect costs; (4) controversy or uncertainty about the effectiveness or relative effectiveness of available clinical strategies or technologies; (5) potential to inform and improve patient or provider decision making; (6) potential to reduce clinically significant variations in the prevention, diagnosis, treatment, or clinical management of a disease or condition, or in the use of a procedure or technology, or in the health outcomes achieved; (7) availability of scientific data to support the study or analysis of the topic; and (8) potential opportunities for rapid implementation.

Submission Process

Nominations of topics and suggestions for organization of the Centers should focus on broad aspects of the legislative program as set out above. For each topic nominated, nominators should provide a rationale and any available supporting evidence reflecting the importance and clinical relevance of the topic and should indicate the potential usefulness of the research in improving the quality of health care while reducing the cost of health care through—the appropriate use of drugs, biological products, or devices; and the prevention of adverse effects of drugs, biological products, and devices; and the consequences of such effects.

Submissions should be brief (1–2 pages) and may be in the form of a letter or e-mail, preferable along with an electronic file in a standard work processing format on a 3½ floppy disk. Submissions should provide:

- A broadly defined topic or idea for organization and implementation of the CERTS, with specific questions to be answered that will establish the focus and boundaries of the research.

• The availability of data and/or, any information on product utilization, cost, the incidence, prevalence, and/or severity of the particular disease, health condition, adverse event or medical error relevant to the topic being nominated.

• Include, if relevant, the significance to Federal Health Programs or underserved populations; or an indication of how the research results or Center activities might be used within the professional or organizational setting.

AHCPR will not reply to individual responses, but will consider all responses in developing the CERTS program and selecting topics for study. AHCPR will review the submissions and supporting information before making final determinations, seeking additional information as appropriate.

Dated: October 26, 1998.

John M. Eisenberg,

Administrator.

[FR Doc. 98–29335 Filed 11–2–98; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research and Subcommittee for Community Affairs: Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meetings.

Name: Advisory Committee for Energy-Related Epidemiologic Research (ACERER).

Times and Dates: 8:30 a.m.–5:15 p.m., November 19, 1998; 8:30 a.m.–12 noon, November 20, 1998.

Place: Radisson Plaza Hotel at Mark Center, 5000 Seminary Road, Alexandria, Virginia 22311, telephone 703/845–1010, fax 703/845–2610.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This committee is charged with providing advice and recommendations to the Secretary, HHS; the Assistant Secretary for Health; the Director, CDC; and the Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), on establishment of a research agenda and the conduct of a research program pertaining to energy-related analytic epidemiologic studies.

Matters to be Discussed: Agenda items will include update presentations from the National Institute for Occupational Safety and Health (NIOSH) and ATSDR on the progress of current studies; an update by the National Center for Environmental Health (NCEH) on coordination of activities with the National Cancer Institute (NCI); a presentation by NCI on Chernobyl, Radio Epi Tables and Ethel Gilbert's Research; a discussion by a panel of risk communications professionals on recommendations made by the National Academy of Sciences/Institutes of Medicine on the NCI report; and a discussion of committee recommendations and public involvement activities.

Agenda items are subject to change as priorities dictate.

Name: ACERER Subcommittee for Community Affairs.

Times and Dates: 1 p.m.–5 p.m., November 20, 1998; 8:30 a.m.–5 p.m., November 21, 1998.

Place: Radisson Plaza Hotel at Mark Center, 5000 Seminary Road, Alexandria, Virginia 22311, telephone 703/845–1010, fax 703/845–2610.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: This subcommittee will advise ACERER on matters related to community needs and will report back to the Agency through the full committee.

Matters to be Discussed: Agenda items will include update presentations from NCEH, NIOSH, and ATSDR on the progress of current studies; a discussion of the September 24, 1998, ACERER meeting and the resolution resulting from that meeting; a discussion of a special report presented by the Tennessean newspaper on health problems in the vicinity of nuclear facilities; and a discussion of committee recommendations and public involvement activities.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Michael J. Sage, Deputy Chief, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE., m/s F–35, Atlanta, Georgia 30341–3724, telephone 770/488–7040, fax 770/488–7044.

Dated: October 28, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–29380 Filed 11–2–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0515]

Agency Information Collection Activities; Announcement of OMB Approval; Amendments to Humanitarian Use Device (HUD) Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Amendments to Humanitarian Use Device (HUD) Requirements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 7, 1998 (63 FR 42404), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0384. The approval expires on October 31, 2001.

Dated: October 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29392 Filed 11–2–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0672]

Guidance on Criteria and Approaches for Postmarket Surveillance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the