

1. *Promistar Financial Corporation*, Johnstown, Pennsylvania; to acquire 100 percent of the voting shares of, and merge with FNH Corporation, Herminie, Pennsylvania, and thereby indirectly acquire voting shares of First National Bank of Herminie, Herminie, Pennsylvania.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. *Porter Bancorp, Inc.*, Shepherdsville, Kentucky; to acquire 100 percent of the voting shares of USAccess Holdings, Inc., Louisville, Kentucky. USAccess Holdings, Inc., Louisville, Kentucky, has applied to become a bank holding company by acquiring at least 66 percent of the voting shares of USAccess Bank, Inc., Louisville, Kentucky.

In connection with this application, USAccess Holdings, Inc., Louisville, Kentucky, and Porter Bancorp, Inc., Shepherdsville, Kentucky have applied to acquire 100 percent of the voting shares of Interim Henry County Bank, Inc., Pleasureville, Kentucky.

C. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *FlatIrons Bank Holding Company*, Loveland, Colorado; to become a bank holding company by acquiring 100 percent of the voting shares of FlatIrons Bank, Boulder, Colorado.

Board of Governors of the Federal Reserve System, May 7, 2001.

Jennifer J. Johnson

Secretary of the Board.

[FR Doc. 01-11872 Filed 5-10-01; 8:45 am]

BILLING CODE 6210-01-S

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank

indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 7, 2001.

A. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. *Ottawa Bancshares, Inc.*, Salina, Kansas; to acquire 100 percent of the voting shares of Admire Bancshares, Inc., Emporia, Kansas, and thereby indirectly acquire Admire Bank, Emporia, Kansas.

Board of Governors of the Federal Reserve System, May 8, 2001.

Jennifer J. Johnson

Secretary of the Board.

[FR Doc. 01-11934 Filed 5-10-00; 8:45 am]

BILLING CODE 6210-01-S

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. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

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 June 4, 2001.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Republic Bancorp, Inc.*, Owosso, Michigan; to acquire NetBank, Inc., Alpharetta, Georgia, and thereby indirectly acquire NetBank, Alpharetta, Georgia, and NetBank Partners, LLC, Alpharetta, Georgia, and thereby engage in operating a savings association, pursuant to § 225.28(b)(4)(ii) of Regulation Y, and in management consulting and counseling activities, pursuant to § 225.28(b)(9)(i)(A)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, May 7, 2001.

Jennifer J. Johnson

Secretary of the Board.

[FR Doc. 01-11873 Filed 5-10-01; 8:45 am]

BILLING CODE 6210-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01097]

Reducing the Impact of Arthritis and Other Rheumatic Conditions; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2001 funds for a cooperative agreement program for Reducing the Impact of Arthritis and Other Rheumatic Conditions. This program addresses the "Healthy People 2010" focus area of Arthritis, Osteoporosis, and Chronic Back Conditions.

The purpose of the program is to further implement the National Arthritis Action Plan: A Public Health Strategy at the state level by building, developing, enhancing, implementing, and evaluating arthritis control and prevention programs. This arthritis program emphasizes State-based

leadership, coordination, and establishment or enhancement of State Health Department capacity to lead efforts to reduce the burden of arthritis within the State. Programmatic efforts should focus on persons affected by arthritis, i.e., persons already experiencing the symptoms of arthritis, their families, and others treating or providing services for persons with arthritis. By targeting persons affected by arthritis, prevention strategies are secondary and tertiary, focusing on prevention of disability and improving quality of life. Primary prevention activities, while worthy, will not be supported in this cooperative agreement.

B. Eligible Applicants

Assistance will be provided only to the health departments of States or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau. The following states are not eligible to apply for funding under this announcement: Alabama, California, Georgia, Florida, Illinois, Minnesota, Missouri, and Utah. These States are currently funded to perform these activities and implement demonstration projects as State Planning Programs under Program Announcement 99074.

Eligibility is limited to State health departments because they are the only organizations capable of reducing the burden of Arthritis on a State-wide basis.

Note: Title 2 of the United States Code, Chapter 26, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

C. Availability of Funds

Approximately \$2.4 million is available in FY 2001 to fund approximately 18 to 24 awards. There will be two levels of activities for this announcement (see below for definitions). Approximately two to six awards will be for the Establishment Level I Program and approximately 16 to 20 awards will be for the Enhanced Establishment Level II Program. It is expected that the average award will be \$100,000 ranging from \$90,000 to \$120,000. It is expected that the awards will begin on or about September 30, 2001, and will be made for a 12-month

budget period within a project period of up to three years. Funding estimates may change. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds. Funds will be provided for a Level 1 and Level 2 Program.

Level 1—Establishment Program objective: is to assist States to establish the basic public health foundation to lead the development and the coordination of a state arthritis program among State Health Departments and other agencies. This includes the formulation of linkages and partnerships dedicated to the development and implementation of a State Plan for Arthritis and the implementation of one or more intervention activities in year two. Applicants eligible for Level 1 funding are those 21 States and Territories not currently receiving CDC funding for arthritis activities. Please refer to Attachment I for a listing of these States.

Level 2—Enhanced Establishment Program: Objective is to build on existing capacity and resources for States currently funded by CDC at level 1. States will be expected to have a current State Plan for Arthritis. Key activities will be to expand and maintain partnerships as appropriate, improve surveillance activities, implement one or more interventions, and coordinate arthritis activities within the State.

Eligible applicants for Level 2 funding are those 30 Establishment States which received CDC funding under program announcement 99074 "Reducing the Burden of Arthritis and Other Rheumatic Conditions."

Applicants may apply for Level 1-Establishment Program or Level 2-Enhanced Establishment Program, but not both.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1A. or 1B. (Recipient Activities), as appropriate, and CDC will be responsible for the activities listed under 2. (CDC Activities).

1A. Recipient Activities Level 1—Establishment Programs

a. **Staffing:** Establish a full-time arthritis program manager to oversee arthritis program activities and to promote an arthritis program within the State.

b. **Partnerships:** Establish an advisory group or coalition to guide, review, and provide direction for the State in all

activities directed at reducing the burden of arthritis.

The advisory group, at a minimum, should include the local chapter(s) of the Arthritis Foundation. In addition, the state should consider the following as members of the advisory board or coalition:

(1) Individuals with expertise in arthritis;

(2) Agencies/organizations with activities relevant to arthritis, resources for arthritis activities, and access to target populations (e.g., Area Agencies on Aging, Medicaid/Medicare, managed care organizations, American Association of Retired Persons, senior centers, and faith communities); and

(3) Persons with arthritis or family members of persons with arthritis. As appropriate, States should establish internal workgroups with other components of State government that are directly or indirectly involved in some aspect of arthritis control and prevention.

c. **Surveillance:** Define and monitor the burden of arthritis using the Behavioral Risk Factor Surveillance System (BRFSS) and other state-based data that contain information on arthritis. By the end of year two, States are encouraged to issue a State of Arthritis Report using, at a minimum, 2001 BRFSS arthritis data. Arthritis data will be collected by all states in calendar year 2001 through the BRFSS.

d. **State Plan:** Develop a State Plan for Arthritis that outlines a proposed framework for activities to reduce the burden of arthritis. This document should be planned with partners and include activities to be implemented by the partners. The plan should not address health department activities only.

e. **Interventions:** During year two, implement one or more strategies consistent with the Public Health Framework for Arthritis (Attachment II) with a focus on the immediate effects. Therefore, activities should be implemented with a focus on one or both of the following areas:

(1) **Self Management Interventions:** Broaden the reach of evidence-based self management programs, e.g., the Arthritis Self Help Course (ASHC), the promotion of physical activity in individuals with arthritis using land/water-based exercise programs such as People with Arthritis Can Exercise® (PACE) and the Arthritis Foundation Aquatics Program. Applicants may consider other programs for which the applicant determined to be beneficial and effective in reducing the burden of arthritis.

(2) *Health Communications Campaigns*: Develop or utilize health communications interventions that will increase/enhance knowledge and beliefs necessary for appropriate management of arthritis. Communications strategies should be designed to increase self management beliefs and behaviors and to increase the belief that self management is an important part of arthritis management. The communications activity can be targeted to people with arthritis and their families, the general public, or health professionals. CDC developed health communication material promoting physical activity may be used. A summary of this material will be posted at www.cdc.gov/nccddphp/arthritis/index.htm. Physician education efforts, while worthy, will not be considered as part of this activity.

1B. Recipient Activities Level 2—Enhanced Establishment Programs

a. *Staffing*: Establish a full time arthritis program manager to oversee arthritis program activities and to promote an arthritis program within the State.

b. *Interventions*: Implement one or more strategies from the State Plan that is consistent with the Public Health Framework for Arthritis (Attachment II) with a focus on the immediate effects as outlined in this framework. Therefore, activities should be implemented with a focus on one or both of the following areas:

(1) *Self Management Interventions*: Broaden the reach of evidence-based self management programs, e.g., the ASHC; the promotion of physical activity in individuals with arthritis using land/water-based exercise programs such as People with Arthritis Can Exercise™ (PACE) and the Arthritis Foundation Aquatics Program. Applicant may consider other programs for which the applicant determined to be beneficial and effective in reducing the burden of arthritis.

(2) *Health Communications Campaigns*: Develop or utilize health communications interventions that will increase/enhance knowledge and beliefs necessary for appropriate management of arthritis. Communications strategies should be designed to increase self management beliefs and behaviors and to increase the belief that self-management is an important part of arthritis management. The communications activity can be targeted to people with arthritis and their families, the general public, and health professionals. CDC developed health communication material promoting physical activity may be used. A

summary of this material will be posted at www.cdc.gov/nccddphp/arthritis/index.htm. Physician education efforts, while worthy, will not be considered as part of this activity.

c. *Partnerships*: Strengthen alliances among current partners. Coordinate or ensure the coordination of activities in the State Plan with other relevant programs, organizations, and groups. Coordinate and collaborate with other entities to maximize the effectiveness, impact, and support for these activities and reduce the potential for unnecessary duplication of effort. States are encouraged to creatively explore other linkage mechanisms and partnership opportunities.

d. *Surveillance*: Manage, analyze, interpret and disseminate State-based arthritis surveillance data and findings. By the end of year, two states are encouraged to issue a State of Arthritis Report using at a minimum, 2001 BRFSS data. Arthritis data was collected by all states in 2001 through the BRFSS. As appropriate, States should expand the existing arthritis surveillance system by examining the availability and/or use of other state-based data sources to supplement the BRFSS. Other data sources may include but are not limited to data from outpatient/ambulatory care settings, managed care organizations, and follow back surveys of BRFSS respondents. Pharmacy data may also prove useful to better define the burden of arthritis within the State.

2. CDC Activities

a. Provide consultation and technical assistance to plan, implement, and evaluate each component of the program.

b. Provide current information on the status of national efforts as they relate to the implementation of recipient activities.

c. As needed, provide technical assistance in the coordination of surveillance efforts and the use of other data systems to measure and characterize the burden of arthritis; provide standard analyses of BRFSS data for states; and provide data for national level comparisons.

d. Facilitate communication among arthritis programs, other government agencies and others involved in arthritis control and prevention efforts.

E. Content (All Applicants)

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program

plan. The main body (narrative) of the application should be no more than 25 pages. The total number of pages should not exceed 60 pages including appendices. The abstract, budget narrative, and federal forms are not included in the page limits. The narrative must be typewritten, double spaced, printed on one side, with 12 point Times New Roman font on 8.5 by 11 inch paper, and with one inch margins. All graphics, maps, overlays, etc., should be in black and white and meet the above criteria. Your application must be submitted UNSTAPLED and UNBOUND.

Abstract

A one-page, single-spaced, typed abstract must be submitted with the application. The heading should include the title of the program, organization, name and address of the project director, telephone number, facsimile number, and e-mail address. The abstract should clearly state which level of activities the applicant is applying for: Level 1—Establishment Program or Level 2—Enhanced Establishment Program. The abstract should briefly list major program elements and activities. A table of contents that provides page numbers for each section should follow the abstract.

Budget

The budget should be reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds. The applicant must include a detailed budget justification. Budgets should include travel for one Arthritis Program staff to attend a two day meeting in Atlanta. Proposed sub-contracts should identify the name of the contractor, if known; describe the services to be performed; provide an itemized budget and justification for the estimated costs of the contract; specify the period of performance; and describe the method of selection. If indirect costs are requested, a copy of the current Indirect Cost Rate Agreement should be included.

F. Submission and Deadline

Application

Submit an original and two copies of CDC 0.1246. Forms are available in the application kit and at the following Internet address: <http://forms.psc.gov/>. On or before July 1, 2001, submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement. Deadline: Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date; or

2. Sent on or before the deadline date and received in time for submission to the independent review group. Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

Late Applications: Applications which do not meet the criteria in 1. or 2. above will be returned to the applicant.

G. Evaluation Criteria (100 Points for Each Level)

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

Level 1—Establishment Programs

1. Need/Current Status (15 Points)

The extent to which the applicant describes the burden of arthritis in the state, identifies what data sources are being used, the barriers the State currently faces in developing and implementing a program for arthritis, and identifies specific needs and resources available for arthritis activities.

2. Work Plan (Total 85 Points)

The extent to which the work plan includes objectives for each of the following areas: Staffing, partnership, surveillance, state plan, and interventions. For each proposed objective, the extent to which there is a description of methods, a time-line for completion, identification of program staff responsible for its achievement, and process evaluation measures. The extent to which all activities are realistic and feasible.

a. Staffing (25 Points)

The degree to which the proposed staff have the relevant background, qualifications, and experience. Specifically, the applicant should:

(1) (15 points) Describe the proposed or existing health department staff's role in promoting an arthritis program within the State, their specific responsibilities, and their level of effort and time. The degree of staff coordination between relevant programs within the state health department; the degree to which the organizational structure supports staff's ability to conduct proposed activities. An organizational chart, job descriptions, and resumes if available, should be included.

(2) (10 points) Include a plan to expedite filling of all positions and provide assurances that such positions will be authorized to be filled by the applicant's personnel system within a reasonable time after receiving funding. If all positions are filled, this criterion will be considered met.

b. Partnerships (20 Points)

(1) (10 points) The extent to which the applicant has included plans for partnerships with the local chapter(s) of the Arthritis Foundation, state and local agencies, federal agencies, and others with an interest in arthritis. If partnerships have been developed, the extent to which the applicant describes the process of development, provides evidence of a viable, ongoing partnership by including copies of agendas for all partnership meetings held for calendar years 1999 and 2000.

(2) (10 points) The extent to which letters of support describe the nature and extent of involvement by outside partners.

c. Surveillance (20 Points)

The extent to which the applicant describes plans to monitor the burden of arthritis within the State using BRFSS data as a minimum. The extent to which the applicant describes future surveillance plans including data to be collected and its programmatic application. The extent to which the applicant provides a plan for the development and dissemination of a State of Arthritis Report.

d. State Plan (10 Points)

The extent to which the applicant describes the process of engaging relevant partners and developing a state arthritis plan. If a state plan has been developed, the extent to which the applicant describes the process of development and provides agendas for planning meetings and the executive summary of the state plan.

e. Interventions (10 Points)

The extent to which the process for selecting the intervention to be implemented in Year two is clearly described and justified. If an existing state plan or partnership has already provided guidance for choice of intervention, the extent to which the applicant describes the target population(s), rationale, and evaluation strategy.

3. Budget (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated

objectives and planned program activities.

Level 2—Enhanced Establishment Program

1. Background/Current Status (15 Points)

The extent to which the applicant adequately describes the burden of arthritis within the State including the definition and data sources used. The extent to which the applicant describes barriers the State currently faces in further developing and implementing programs for the control of arthritis. The extent to which the funds will fill the gaps in the State's arthritis activities.

2. Work Plan (Total 85 Points)

The extent to which the work plan includes objectives for each of the following areas: staffing, partnership, surveillance, and interventions. For each proposed objective, the extent to which there is a description of methods, a time-line for completion, identification of the program staff responsible for its achievement, and process evaluation measures. The extent to which all activities are realistic and feasible.

a. Staffing and Management (25 Points)

The degree to which the existing or proposed staff have the relevant background, qualifications, and experience. Specifically, the applicant should:

(1) (15 points) Describe the existing or proposed health department staff role in promoting an arthritis program within the State; their specific responsibilities, and their level of effort and time. The degree of staff coordination between relevant programs within the state health department; the degree to which the organizational structure supports staff's ability to conduct proposed activities. An organizational chart, job descriptions, and resumes if available, should be included.

(2) (10 points) Describe the plan to expedite filling of all positions and provide assurances that such positions will be authorized to be filled by the applicant's personnel system within a reasonable time after receiving funding. If all positions are filled, this criterion will be considered met.

b. Partnerships (20 Points)

(1) (10 points) The extent to which the applicant describes the roles of advisory groups, partnerships, or coalition in the development and implementation of activities in the State Plan for Arthritis. The extent to which letters of support describe the nature and extent of involvement by outside partners.

(2) (10 points) The extent to which the applicant has shown that partnerships have been ongoing and viable and have included copies of the following: (1) Agendas for all partnership meetings for calendar years 1999 and 2000; and (2) the executive summary and table of contents from the State Plan for Arthritis.

c. Surveillance (15 Points)

The extent to which the applicant describes the status of existing state-based arthritis surveillance. The extent to which the applicant describes future surveillance plans including data to be collected, the rationale for its selection and its programmatic application.

d. Interventions (25 Points)

The extent to which the applicant describes the proposed intervention(s) activity, the rationale for selection, the target population, the appropriateness of the intervention for the target population, and the implementation and evaluation strategies.

3. Budget (Not Scored)

The extent to which the applicant provides a detailed budget and narrative justification consistent with stated objectives and planned program activities.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Semi-annual progress reports.
2. Financial status report, no more than 90 days after the end of the budget period;
3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment III in the application kit.

- AR-7 Executive Order 12372 Review
- AR-9 Paperwork Reduction Act Requirements
- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317 of the Public Health Service Act, [42 U.S.C. section

241(a) and 247(b)], as amended. The Catalog of Federal Domestic Assistance number is 93.945.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—<http://www.cdc.gov> Click on "Funding" then "Grants and Cooperative Agreements". Should you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Michelle Copeland, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, Program Announcement 01097, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341-4146, Telephone number: (770) 488-2686, E-mail address: stc8@cdc.gov

For program technical assistance, contact: Sakeena Smith, MPH, Senior Project Officer, Arthritis Program, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Mailstop K-45, Atlanta, GA 30341, Telephone number: (770) 488-5440, E-mail address: SSmith1@cdc.gov

Dated: May 7, 2001.

Henry S. Cassell III,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01-11896 Filed 5-10-01; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E-0465]

Determination of Regulatory Review Period for Purposes of Patent Extension; Baycol

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Baycol and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce,

for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Regulatory Policy Staff (HFD-007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued) FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Baycol (cerivastatin sodium). Baycol is indicated as an adjunct to diet for the reduction of elevated total and LDL cholesterol levels in patients with primary hypercholesterolemia and mixed dyslipidemia (Frederickson Types IIa and IIb) when the response to dietary restriction of saturated fat and cholesterol and other nonpharmacological measures alone has been inadequate. Subsequent to this approval, the Patent and Trademark