

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/](http://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 April 23, 2001.

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

1. *C.C. Bancorp, Inc.*, Little Valley, New York; to become a bank holding company by acquiring 100 percent of the voting shares of Cattaraugus County Bank, Little Valley, New York.

**B. Federal Reserve Bank of Philadelphia** (Michael E. Collins, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105-1521:

1. *Fulton Financial Corporation*, Lancaster, Pennsylvania; to merge with Drovers Bancshares Corporation, York, Pennsylvania, and thereby acquire The Drovers and Mechanics Bank, York, Pennsylvania.

Board of Governors of the Federal Reserve System, March 26, 2001.

**Robert deV. Frierson**

*Associate Secretary of the Board.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration on Aging

#### Agency Information Collection Activities: Proposed Submission to the Office of Management and Budget (OMB) for Clearance; Comment Request; Extension of a Currently Approved Information Collection

**AGENCY:** Administration on Aging, HHS.

The Administration on Aging (AoA), Department of Health and Human Services, provides an opportunity for comment on the following proposal for the collection of information in compliance with the Paperwork Reduction Act (PRA; Public Law 96-511):

*Title of Information Collection:* Performance Progress Reports for Title IV Grantees.

*Type of Request:* Extension of use of the report, with no revision.

*Use:* Extension of reporting format for use by Title IV grantees in reporting on activities of their Title IV Discretionary Funds Projects as required under Title IV of the Older Americans Act, as amended.

*Frequency:* Semi-annually.

*Respondents:* States, public agencies, private nonprofit agencies, institutions of higher education, and organizations, including tribal organizations.

*Estimated Number of Responses:* 160.

*Total Estimated Burden Hours:* 3,200.

*Additional Information or Comments:* The Administration on Aging plans to submit to the Office of Management and Budget for approval, an extension, with no revisions, of a reporting form and instructions for the Title IV Discretionary Funds Program, pursuant to requirements in Title IV of the Older Americans Act. Written comments and recommendations for the proposed information collection should be sent within 60 days of the publication of this notice directly to the following address: Office of Program Development, Administration on Aging, Attention: Judy Satine, 330 Independence Avenue, SW., Washington, DC 20201.

Dated: March 22, 2001.

**Norman L. Thompson,**

*Acting Principal Deputy Assistant Secretary for Aging.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration on Aging

[Program Announcement No. AoA-01-03]

#### Fiscal Year 2001 Program Announcement; Availability of Funds and Notice Regarding Applications

**AGENCY:** Administration on Aging, HHS.

**ACTION:** Request for applications for a Technical Assistance Project for Statewide Senior Legal Hotlines to provide technical assistance and guidance to support statewide senior legal hotlines programs.

**SUMMARY:** The Administration on Aging announces that under this program announcement it will hold a competition for a grant award for *one* (1) project at a federal share of approximately \$90,000 to \$100,000 per year for a project period of three years. The purpose of the project is to provide appropriate technical assistance to statewide senior legal hotline programs aimed at advancing the quality and accessibility of the legal assistance provided to older people.

The deadline date for the submission of applications is May 11, 2001. Eligibility for grant awards is limited to public and/or nonprofit agencies, organizations, and institutions experienced in providing legal assistance to older persons.

Application kits are available by writing to the Department of Health and Human Services, Administration on Aging, Office of Program Development, 330 Independence Avenue, SW., Room 4264, Washington, DC 20201, by calling 202/619-2987, or on the web at <http://www.aoa.gov/t4/fy2001>.

Dated: March 23, 2001.

**Norman L. Thompson,**

*Acting Principal Deputy Assistant Secretary for Aging.*

[FR Doc. 01-7905 Filed 3-29-01; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 01N-0132]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Institutional Review Boards

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's protection of human subjects recordkeeping and reporting requirements for institutional review boards (IRB's). IRB's are groups composed of members of varying backgrounds that are charged with reviewing the ethics and risk/benefit aspects of clinical studies involving human subjects to assure that the rights and welfare of human subjects are adequately protected.

**DATES:** Submit written or electronic comments on the collection of information by May 29, 2001.

**ADDRESSES:** Submit electronic comments on the collection of information via the Internet at <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250),

Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

**Institutional Review Boards—Section 56.115 (21 CFR 56.115) (OMB Control No. 0910-0130)—Extension**

When reviewing clinical research studies regulated by FDA, IRB's are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the basis for requiring changes in or disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRB's to determine whether IRB's and clinical investigators are providing adequate protections to human subjects participating in clinical research.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
56.115	2,000	14.6	29,200	4.5	131,400
Total					131,400

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The recordkeeping requirement burden is based on the following formula: Approximately 2,000 IRB's review FDA-regulated research involving human subjects annually. The burden for each of the paragraphs under § 56.115 has been considered as one estimated burden. Each paragraph cannot reasonably be segregated from one another because all are interrelated. FDA has about 2,000 IRB's in its

inventory. The 2,000 IRB's meet on an average of 14.6 times annually. The agency estimates that approximately 4.5 hours of person time per meeting are required to transcribe and type the minutes of the meeting; to maintain records of continuing review activities; and to make copies of all correspondence between the IRB and investigative member records, and

written IRB procedures that are approximately five pages per IRB.

Dated: March 23, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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