

Board of Governors of the Federal Reserve System, April 23, 2009.
Robert deV. Frierson,
Deputy Secretary of the Board.
 [FR Doc. E9-9627 Filed 4-27-09; 8:45 am]
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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 applications 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 May 22, 2009.

A. Federal Reserve Bank of Atlanta (Steve Foley, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. *Piedmont Bancorp, Inc.*, Norcross, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Republic Bank of Georgia, Lawrenceville, Georgia.

B. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) P.O. Box 442, St. Louis, Missouri 63166-2034:

1. *Southern Missouri Bancorp, Inc.*, Poplar Bluff, Missouri; to acquire 100 percent of the voting shares of Southern Bank of Commerce, Paragould, Arkansas.

Board of Governors of the Federal Reserve System, April 23, 2009.

Robert deV. Frierson,
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The Impact of Clinical Research Training and Medical Education at the Clinical Center on Physician Careers in Academia and Clinical Research

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Clinical Center, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal**

Register on January 2, 2009, page 112 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: The Impact of Clinical Research Training and Medical Education at the Clinical Center on Physician Careers in Academia and Clinical Research. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will assess the value of the training programs administered by the Office of Clinical Research Training and Medical Education. The primary objective of the survey is to determine if training programs have had an impact on whether the trainees are performing clinical research, hold an academic appointment, have National Institutes of Health funding sources as well as to obtain information from the trainees as to what part of the National Institutes of Health medical education program they feel could be improved upon, the quality of the mentoring program, and how their National Institutes of Health training has contributed to their current clinical competence. *Frequency of Response:* On occasion. *Affected Public:* Individuals and businesses. *Type of Respondents:* Physicians, dentists, medical students, dental students, nurses, and Ph.D.s. The annual reporting burden is as follows: *Estimated Number of Respondents:* 825. *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* 0.5; and *Estimated Total Annual Burden Hours Requested:* 412.5.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Doctoral Level	625	1	0.5	312.5
Students	100	1	0.5	50
Nurses	100	1	0.5	50
Total				412.5

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper

performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who

are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Linda Wisniewski, Office of Clinical Research Training and Medical Education, Clinical Center, Building 10, Room: 1N252B, 9000 Rockville Pike, Bethesda, MD 20892, or call 301-496-9425 or E-mail your request, including your address to: wisniewskil@cc.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: April 16, 2009.

Laura Lee,

Project Clearance Liaison, Warren Grant Magnuson Clinical Center, National Institutes of Health.

[FR Doc. E9-9688 Filed 4-27-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0565]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 28, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0396. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3792.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level—(OMB Control Number 0910-0396)—Extension

This information collection approval request is for an FDA guidance on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that cannot be resolved at the division level. The guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue(s) presented. The guidance provides information on how the agency will interpret and apply provisions of the existing regulations regarding internal agency review of decisions (§ 10.75) and dispute resolution during the investigational new drug (IND) process (§ 312.48) and the new drug application/abbreviated new drug application (NDA/ANDA) process (§ 314.103). In addition, the guidance provides information on how the agency will interpret and apply the specific Prescription Drug User Fee Act (PDUFA) goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the agency, CDER, and CBER. All agency decisions on such matters are based on information in the administrative file

(§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in parts 312 (OMB Control No. 0910-0014), 314 (OMB Control No. 0910-0001), and part 601 (21 CFR part 601) (OMB Control No. 0910-0338), which specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. While FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the dispute. The guidance describes the following collection of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations (§§ 312.23(11)(d), 314.50, 314.94, and 601.2) state that information provided to the agency as part of an IND, NDA, ANDA, or BLA is to be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571—OMB Control No. 0910-0014, and FDA Form 356h—OMB Control No. 0910-0338.

In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted as an amendment in this manner for two reasons: To ensure that each request is kept in the administrative file with the entire underlying application and to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the resolution of the dispute and to