Report title: The Recordkeeping, Reporting and Disclosure Requirements in Connection with Regulation BB (Community Reinvestment Act (CRA)).

Agency form number: Reg BB.

OMB control number: 7100–0197.

Frequency: Annually.

Reporters: State member banks (SMBs).

Annual reporting hours: 52,127 hours.

Estimated average hours per response: Recordkeeping Requirement, small business and small farm loan register, 219 hours. Optional Recordkeeping Requirements, consumer loan data, 326 hours and other loan data, 25 hours. Reporting Requirements, assessment area delineation, 2 hours; small business and small farm loan data, 8 hours; community development loan data, 13 hours; and Home Mortgage Disclosure Act (HMDA) out of Metropolitan Statistical Areas (MSA) loan data, 253 hours. Optional Reporting Requirements, data on lending by a consortium or third party, 17 hours; affiliate lending data, 38 hours; strategic plan, 275 hours; and request for designation as a wholesale or limited purpose bank, 4 hours. Disclosure Requirement, public file, 10 hours.

Number of respondents: Recordkeeping Requirement, small business and small farm loan register, 72. Optional Recordkeeping Requirements, consumer loan data, 24 and other loan data, 4. Reporting Requirements, assessment area delineation, 72; small business and small farm loan data, 72; community development loan data, 72; and HMDA out of MSA loan data, 72. Optional Reporting Requirements, data on lending by a consortium or third party, 6; affiliate lending data, 4; strategic plan, 1; and request for designation as a wholesale or limited purpose bank, 1. Disclosure Requirement, public file, 803.

General description of report: This information collection is authorized by section 806 of the CRA which permits the board to issue regulations to carry out the purpose of CRA (12 U.S.C. 2905), Section 11 of the Federal Reserve Act (FRA), which permits the Board to require such statements as reports of SMBs as it deems necessary (12 U.S.C. 248(a)(1)), and section 9 of the FRA, which permits the Board to examine SMBs (12 U.S.C. 325). The requirements are generally mandatory, depending on bank size and other factors. The data that are reported to the Federal Reserve are not considered confidential.

Abstract: This submission covers an extension of the Federal Reserve's currently approved information collections in their CRA regulations (12 CFR part 228). The submission involves no change to the regulation or to the information collection. The Federal Reserve System needs the information collected to fulfill their obligations under the CRA to evaluate and assign ratings to the performance of institutions in connection with helping to meet the credit needs of their communities, including low- and moderate-income neighborhoods, consistent with safe and sound banking practices. The Federal Reserve System uses the information in the examination process and in evaluating applications for mergers, branches, and certain other corporate activities. Financial institutions maintain and provide the information to the Federal Reserve System.

Current Actions: On July 21, 2011, the Federal Reserve published a notice in the **Federal Register** (76 FR 43686) requesting public comment for 60 days on the extension, without revision, of the recordkeeping, reporting and disclosure requirements in connection with Regulation BB. The comment period for this notice expired on September 19, 2011. The Federal Reserve did not receive any comments.

Board of Governors of the Federal Reserve System, October 4, 2011.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2011–26085 Filed 10–7–11; 8:45 am]

BILLING CODE 6210–01–P

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.

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 November 4, 2011.

A. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *SHB Bancorp, Inc.,* Jonesville, Louisiana; to become a bank holding company by acquiring 100 percent of the voting shares of Southern Heritage Bank, Jonesville, Louisiana.

Board of Governors of the Federal Reserve System, October 5, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–26156 Filed 10–7–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Shamarendra Sanyal, PhD Duke University: Based on an inquiry conducted by Duke University (Duke), admissions by the Respondent, and additional analysis conducted by ORI in its oversight review, ORI and Duke found that Dr. Shamarendra Sanyal, former postdoctoral scholar, Duke, engaged in research misconduct by falsifying data in a grant application submitted to the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).

Specifically, ORI found that the Respondent falsified Figure 2C of grant application 1 R01 HL107901–01, ''Store-operated calcium entry in airway inflammation,'' by altering the gain settings in the instrument used to measure store-operated current (SOC) densities in a whole cell patch clamp experiment comparing Stim $1^{+/-}$ mouse airway cells and wild type mouse airway cells. Respondent also

falsified the calcium response data in Figure 5A (right panel) of the grant application referenced above by adding ATP as a reagent to the mouse airway epithelial cells to sharpen the results purported to be caused by PGN without disclosing that ATP had been added and without disclosing that ATP was not added to the control sample.

The questioned research was not submitted for publication.

Dr. Sanyal has entered into a Voluntary Settlement Agreement with ORI and Duke, in which he voluntarily agreed to the administrative actions set forth below. The administrative actions are required for two (2) years beginning on the date of Dr. Sanyal's employment in a research position in which he receives or applies for PHS support on or after the effective date of the Agreement (September 16, 2011); however, if he has not obtained employment in a research position in which he receives or applies for PHS support within three (3) years of the effective date of the Agreement, the administrative actions set forth below will no longer apply. Dr. Sanyal has voluntarily agreed:

(1) To have his research supervised as described below and to notify his employer(s)/institutions(s) of the terms of this supervision; Respondent agrees to ensure that prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS supported research, the institution employing him will submit a plan for supervision of Respondent's duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that he will not participate in any PHS supported research from the effective date of this Agreement until a plan for supervision is submitted to and approved by ORI; Respondent agrees to be responsible for maintaining compliance with the agreed upon plan for supervision;

(2) that any institution employing him must submit, in conjunction with each application for PHS funds, or report, manuscript, or contract involving PHS supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

John Dahlberg,

Director, Division of Investigative Oversight, Office of Research Integrity.

[FR Doc. 2011–26127 Filed 10–7–11; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–3180–N2]

Food and Drug Administration

[Docket No. FDA–2010–N–0308]

Pilot Program for Parallel Review of Medical Products

AGENCY: Food and Drug Administration, Centers for Medicare and Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) (the Agencies) are soliciting nominations from sponsors of innovative device technologies to participate in a pilot program for concurrent review of certain FDA premarket review submissions and CMS national coverage determinations. The Agencies announced the intention to initiate a pilot program in the **Federal Register** of September 17, 2010. The Agencies are now providing notice of the procedures for voluntary participation in the pilot program, as well as the guiding principles the Agencies intend to follow.

DATES: *Effective Date:* November 10, 2011.

FOR FURTHER INFORMATION CONTACT:

For device sponsors interested in requesting voluntary parallel review:

Markham C. Luke, Center for Devices and Radiological Health, Food and Drug Administration, 301–796–5550, *e-mail: markham.luke@fda.hhs.gov.*

For General questions about parallel review:

Peter Beckerman, Office of Policy, Food and Drug Administration, 301–796–4830, *e-mail: peter.beckerman@fda.hhs.gov* or Tamara Syrek Jensen, Centers for Medicare and Medicaid Services, 410–786–3529, *e-mail: Tamara.Syrekjensen@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. Parallel Review Proposal

As discussed in the September 17, 2010, **Federal Register** notice (75 FR 57045), parallel review is intended to reduce the time between FDA marketing approval and CMS national coverage determinations, thereby improving the quality of patient health care by facilitating earlier access to innovative medical products for Medicare beneficiaries. In the notice of September 17, 2010, we solicited comments on parallel review of submissions to FDA and CMS for regulated medical products. We also stated our intention to initiate a pilot program for parallel review of devices. The Agencies received 36 comments before the comment period closed on December 16, 2010. The public comments can be found at: *http://www.regulations.gov,* identified by docket number FDA–2010–N–0308. Major themes of the comments included, among others: Parallel review should be sponsor/requester initiated, voluntary, and include an option to opt out of a national coverage determination (NCD); agencies should clarify the confidentiality standards for data sharing between the Agencies; and agencies should establish clear and concise guidelines on the procedures and a timeline for parallel review. These comments have informed the parallel review pilot program for medical devices we are announcing in this notice. We also intend to seek input and feedback from candidate sponsor/requesters who participate in the pilot. Current information describing the FDA–CMS Parallel Review Pilot Program for Medical Devices can be found at the following Web site: *http://www.parallel-review.fda.gov.*

B. Expected Benefits of Parallel Review

The expected benefits of an FDA–CMS parallel review program were discussed in the September 17, 2010, notice. The anticipated benefits include facilitating development of innovative new products and increased efficiency in the Agencies' review processes.

It has come to our attention that innovators have generally focused solely on obtaining FDA approval, only to later realize that Medicare payment may not automatically be forthcoming.

As stated in the notice of September 17, 2010, parallel review will serve the