

(15) days after publication of this notice in the **Federal Register**.

Agreement No.: 011962-009.

Title: Consolidated Chassis

Management Pool Agreement.

Parties: The Ocean Carrier Equipment Management Association and its member lines; the Association's subsidiary Consolidated Chassis Management LLC and its affiliates; CCM Holdings LLC; CCM Pools LLC and its subsidiaries; Matson Navigation Co.; and Westwood Shipping Lines.

By Order of the Federal Maritime Commission.

Dated: March 8, 2013.

Karen V. Gregory,

Secretary.

[FR Doc. 2013-05779 Filed 3-12-13; 8:45 am]

BILLING CODE 6730-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than March 28, 2013.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Marjorie Jane Danielson, Freeport, Maine, and Anne Danielson Pick, St. Paul, Minnesota, both as individuals, and The Clifford and Marjorie Danielson for M. Jane Danielson Child's Trust; The Clifford and Marjorie Danielson for M. Jane Danielson's Descendants Trust; The Clifford and Marjorie Danielson for Anne Pick Child's Trust; The Clifford and Marjorie Danielson for Anne Pick's Descendants Trust*, all of Sycamore, Illinois, as a group acting in concert to retain voting shares of NI Bancshares, Corporation, and thereby indirectly retain voting shares of The National Bank & Trust Company, both in Sycamore, Illinois.

Board of Governors of the Federal Reserve System, March 8, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013-05768 Filed 3-12-13; 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 applications will also 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 April 8, 2013.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *Southern BancShares (N.C.), Inc.*, Mount Olive, North Carolina; to merge with Heritage BancShares, Inc., and thereby indirectly acquire The Heritage Bank, both in Lucama, North Carolina.

Board of Governors of the Federal Reserve System, March 8, 2013.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2013-05769 Filed 3-12-13; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0980]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

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 April 12, 2013.

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: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0584. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@fda.hhs.gov.

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 on Reagents for Detection of Specific Novel Influenza A Viruses—(OMB Control Number 0910-0584—Extension

In accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c), FDA evaluated an application for an in vitro diagnostic device for detection of influenza subtype H5 (Asian lineage), commonly known as avian flu. FDA concluded that this device is properly classified into class II in accordance with section 513(a)(1)(B) of the FD&C Act, because it is a device for which the general controls by themselves are

insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance. The statute permits FDA to establish as special controls many different things, including postmarket surveillance, development and dissemination of guidance recommendations, and “other appropriate actions as the Secretary deems necessary” (section 513(a)(1)(B) of the FD&C Act). This information collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses.

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on February 3, 2006, establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification was codified in 21 CFR 866.3332, a regulation that describes the new classification for reagents for detection of specific novel influenza A viruses and sets forth the special controls that help to provide a reasonable assurance

of the safety and effectiveness of devices classified under that regulation. The regulation refers to the special controls guidance document entitled “Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses,” which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents. The guidance document recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time. As updated sequences for novel influenza A viruses become available from the World Health Organization, National Institutes of Health, and other public health entities, sponsors of reagents for detection of specific novel influenza A viruses will collect this information, compare them with the primer/probe sequences in their devices, and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1).

These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g), to determine if any design changes may be necessary.

FDA estimates that 10 respondents will be affected annually. Each respondent will collect this information twice per year; each response is estimated to take 15 hours. This results in a total data collection burden of 300 hours. The guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

In the **Federal Register** of September 25, 2012 (77 FR 58997), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

FD&C Act section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
513(g)	10	2	20	15	300

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

Dated: March 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-05722 Filed 3-12-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0010]

Cooperative Agreement To Support Regulatory Research Related to Food and Drug Administration Commitments Under the 2012 Prescription Drug User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its intention to accept and consider a single source application for award of a

cooperative agreement to the Brookings Institution’s Engelberg Center for Health Care Reform (EHCRCR) in support of efforts to inform major initiatives for process improvement and regulatory science related to FDA commitments under the 2012 reauthorization of the Prescription Drug User Fee Act (PDUFA V).

DATES: Important dates are as follows:

1. The application due date is April 15, 2013.
2. The anticipated start date is June 1, 2013.
3. The expiration date is April 16, 2013.

For Further Information and Additional Requirements Contact:

Adam Kroetsch, Office of Planning and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993, 301-796-3842, Adam.Kroetsch@fda.hhs.gov;

or

Yemisi Akinneye, Office of Acquisitions and Grants Services, Food and Drug Administration, 5630 Fishers Lane, HFA 500, Rm. 2037, Rockville, MD 20857, 301-827-0079, Oluyemisi.Akinneye@fda.hhs.gov.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://grants2.nih.gov/grants/guide/and/or> <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm093567.htm>.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-13-005; 93.103.

A. Background

The FDA Center for Drug Evaluation and Research (CDER) seeks to support efforts to research, identify key issues, and convene appropriate subject matter experts to help inform major initiatives for process improvement and regulatory