

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 August 11, 2015.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Happy Bancshares, Inc., Employee Stock Ownership Plan with 401(k) Provisions*, Vicki Wilmarth, Trustee, Amarillo, Texas; to acquire voting shares of Happy Bancshares, Inc., Canyon, Texas, and thereby indirectly acquire voting shares of Happy State Bank, Happy, Texas.

Board of Governors of the Federal Reserve System, July 22, 2015.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2015-18310 Filed 7-24-15; 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 August 21, 2015.

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

1. *Heartland Financial USA, Inc.*, Dubuque, Iowa; to acquire 100 percent of the voting shares of Premier Valley Bank, Fresno, California.

B. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Stearns Financial Services, Inc., Employee Stock Ownership Plan*, Saint Cloud, Minnesota, to retain and acquire additional voting shares, for a total up to 32.48 percent of the voting shares of Stearns Financial Services, Inc., Saint Cloud, Minnesota, and thereby indirectly increase its control of Stearns Bank National Association, Saint Cloud, Minnesota, Stearns Bank of Upsala, National Association, Upsala, Minnesota, and Stearns Bank of Holdingford, National Association, Holdingford, Minnesota.

Board of Governors of the Federal Reserve System, July 22, 2015.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2015-18312 Filed 7-24-15; 8:45 am]

**BILLING CODE 6210-01-P**

## FEDERAL RESERVE SYSTEM

### Notice of Proposals To Engage in or To Acquire Companies 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.

Unless otherwise noted, comments regarding the notices must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than August 21, 2015.

A. Federal Reserve Bank of Boston (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210-2204:

1. *South Shore Mutual Holding Company*, Weymouth, Massachusetts; to acquire Satuit MHC, and indirectly acquire Scituate Federal Savings Bank, both in Scituate, Massachusetts, and thereby engage in operating a savings and loan association, pursuant to section 225.28(b)(4)(ii).

Board of Governors of the Federal Reserve System, July 22, 2015.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2015-18311 Filed 7-24-15; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60 Day-15-15AWV; Docket No. CDC-2015-0060]

### Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on an information collection pertaining to the collection of tuberculosis-related information from United States Panel Physicians.

**DATES:** Written comments must be received on or before September 25, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0060 by any of the following methods:

- *Federal eRulemaking Portal:* [Regulation.gov](http://www.Regulation.gov). Follow the instructions for submitting comments.

• *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

**Please note:** All public comment should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: [omb@cdc.gov](mailto:omb@cdc.gov).

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the

use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

#### **Proposed Project**

Information Collection for Tuberculosis Data from Panel Physicians—An Existing Collection in Use Without an OMB Control Number—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

#### *Background and Brief Description*

The Centers for Disease Control and Prevention's (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), Immigrant, Refugee, and Migrant Health Branch (IRMH), requests approval for a new information collection to request quarterly reports on certain tuberculosis data from U.S. panel physicians.

The respondents are panel physicians. More than 760 panel physicians perform overseas pre-departure medical examinations in accordance with requirements, referred to as technical instructions, provided by the Centers for Disease Control and Prevention's Division of Global Migration and Quarantine, Quality Assessment Program (QAP). The role of QAP is to assist and guide panel physicians in the implementation of the Technical Instructions; evaluate the quality of the overseas medical examination for U.S.-bound immigrants and refugees; assess potential panel physician sites; and

provide recommendations to the U.S. Department of State in matters of immigrant medical screening.

To achieve DGMQ's mission, the Immigrant, Refugee and Migrant Health branch (IRMH) works with domestic and international programs to improve the health of U.S.-bound immigrants and refugees to protect the U.S. public by preventing the importation of infectious disease. These goals are accomplished through IRMH's oversight of medical exams required for all U.S.-bound immigrants and refugees who seek permanent residence in the U.S. IRMH is responsible for assisting and training the international panel physicians with the implementation of medical exam Technical Instructions (TI). Technical Instructions are detailed requirements and national policies regarding the medical screening and treatment of all U.S.-bound immigrants and refugees.

Screening for tuberculosis (TB) is a particularly important component of the immigration medical exam and allows panel physicians to diagnose active TB disease prior to arrival in the United States. As part of the Technical Instructions requirements, panel physicians perform chest x-rays and laboratory tests that aid in the identification of tuberculosis infection (Class B1 applicants) and diagnosis of active tuberculosis disease (Class A, inadmissible applicants). CDC uses these classifications to report new immigrant and refugee arrivals with a higher risk of developing TB disease to U.S. state and local health departments for further follow-up. Some information that panel physicians collect as part of the medical exam is not reported on the standard Department of State forms (DS-forms), thereby preventing CDC from evaluating TB trends in globally mobile populations and monitoring program effectiveness.

Currently, CDC is requesting this data to be sent by panel physicians once per year. The consequences of reducing this frequency would be the loss of monitoring program impact and TB burdens in mobile populations and immigrants and refugees coming to the United States on an annual basis. There is no cost to the respondents other than their time.

## ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
International Panel Physicians (All sites).	TB Indicators Excel Spreadsheet.	353	1	7.5	2,648
<b>TOTAL</b> .....	.....	.....	.....	.....	<b>2,648</b>

**Leroy A. Richardson,**

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2015-18301 Filed 7-24-15; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0987]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled, "Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On December 10, 2014, the Agency submitted a proposed collection of information entitled, "Generic Clearance for the Collection of Qualitative Data on Tobacco Products and Communications" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number

0910-0796. The approval expires on June 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 22, 2015.

**Leslie Kux,**

Associate Commissioner for Policy.

[FR Doc. 2015-18295 Filed 7-24-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-D-0103]

#### Analytical Procedures and Methods Validation for Drugs and Biologics; Guidance for Industry; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Analytical Procedures and Methods Validation for Drugs and Biologics." This guidance supersedes the draft of the same name that published on February 19, 2014, and replaces the 2000 draft guidance for industry on "Analytical Procedures and Methods Validation" and the 1987 FDA guidance for industry on "Submitting Samples and Analytical Data for Methods Validation." This guidance discusses how to submit analytical procedures and methods validation data to support the documentation of the identity, strength, quality, purity, and potency of drug substances and drug products.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th

Floor, Silver Spring, MD 20993, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Lucinda Buhse, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2130, Silver Spring, MD 20993-0002, 240-402-4595, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled "Analytical Procedures and Methods Validation for Drugs and Biologics." This guidance supersedes the draft of the same name that published on February 19, 2014, and replaces the 2000 draft guidance for industry on "Analytical Procedures and Methods Validation" and the 1987 FDA guidance for industry on "Submitting Samples and Analytical Data for Methods Validation." It discusses how to submit analytical procedures and methods validation data to support the documentation of the identity, strength, quality, purity, and potency of drug substances and drug products, and how to assemble information and present