institutions that are located in the Caribbean or the United Kingdom.

Estimated annual reporting hours: 574 hours.

Estimated average hours per response: 3.5 hours.

Number of respondents: 41.

General description of report: This information collection is required (12 U.S.C. 248(a)(2), 461, 602, and 625) and is given confidential treatment (5 U.S.C. 552(b)(4)).

Abstract: The FR 2502q collects data quarterly on the geographic distribution of the assets and liabilities of major U.K. or Caribbean branches and subsidiaries of U.S. commercial banks, bank holding companies, including financial holding companies, and of banking Edge and agreement corporations. Data from this reporting form comprise a piece of the flow of funds data that are compiled by the Federal Reserve. FR 2502q data also helps the Federal Reserve understand the nature of activities of foreign offices of U.S. banks, particularly the scope of cross-border activity that is conducted by different foreign offices in the United Kingdom and the Caribbean.

Current Actions: On December 8, 2011 the Federal Reserve published a notice in the **Federal Register** (76 FR 76730) requesting public comment for 60 days on the extension, with revision, of the Quarterly Report of Assets and Liabilities of Large Foreign Offices of U.S. Banks. The comment period for this notice expired on February 6, 2012. The Federal Reserve did not receive any comments. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, February 22, 2012.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2012–4527 Filed 2–27–12; 8:45 am]

BILLING CODE 6210–01–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 14, 2012.

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

1. *Perry Hodgson, Alexander Hodgson, and Raymond Hodgson,* all of Charlevoix, Michigan; to join the existing Hodgson control group and to retain and acquire voting shares of Charlevoix First Corporation, and indirectly retain and acquire voting shares of Charlevoix State Bank, Charlevoix, Michigan.

Board of Governors of the Federal Reserve System, February 23, 2012.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2012–4616 Filed 2–27–12; 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 March 23, 2012.

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

1. *SCBT Financial Corporation,* Columbia, South Carolina; to acquire 100 percent of the voting shares of Peoples Bancorporation, Inc., and thereby indirectly acquire voting shares of The Peoples National Bank, both in Easley, South Carolina, Bank of Anderson, NA, Anderson, South Carolina, and Seneca National Bank, Seneca, South Carolina.

B. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *United Group of Central Florida II, LLC,* Longwood, Florida, to become a bank holding company by acquiring 100 percent of the voting shares of Citizens Bancorp of Oviedo, Inc., and thereby indirectly acquire voting shares of Citizens Bank of Florida, both in Oviedo, Florida.

Board of Governors of the Federal Reserve System, February 23, 2012.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2012–4617 Filed 2–27–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–12–12EL]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 and send comments to Kimberly S. Lane, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

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; and (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. Written comments should be received within 60 days of this notice.

Proposed Project

Critical Thinking and Cultural Affirmation (CTCA): Evaluation of a Locally Developed HIV Prevention Intervention—New—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2005, the Centers for Disease Control and Prevention (CDC) reported that 80,187 African Americans were diagnosed with HIV/AIDS, which represents 51% of persons diagnosed. African-American men with HIV/AIDS represented 44% of all cases among males (Centers for Disease Control and Prevention [CDC], 2005). These statistics have been consistently disproportional since the late 1990s, with African Americans bearing the greatest burden of new HIV cases in most regions of the United States. The Centers for Disease Control and Prevention estimates that at the end of 2006, Blacks were disproportionately affected by HIV. The 2006 HIV infection rate in Blacks was nearly twice the rate of Whites (92 out of every 100,000 Blacks compared to 48 per 100,000 Whites and 31 per 100,000 Hispanics). Among males, Black males accounted for the largest number of diagnosed HIV infections and have the highest HIV infection rate of any race/ethnicity group (144 per 100,000, compared to 94 per 100,000 for White males and 50 per 100,000 for Hispanic males.

While many HIV prevention and intervention studies include samples of African-American men and African-American Men who have Sex with Men (AAMSM), beyond demonstrating disparities in seroprevalence between and among racial groups, few have been specifically designed and evaluated for efficacy among African-American men. Because few HIV prevention interventions targeting AAMSM have been developed and rigorously evaluated, while their HIV infection rates remain disproportionately high and continue to rise, identifying effective interventions for AAMSM is a public health imperative.

The purpose of this project is to test the efficacy of an HIV transmission prevention intervention for reducing sexual risk among African American men who have sex with men in Chicago, Illinois. The intervention is a 3-day weekend retreat, group-level CTCA intervention that combines cultural affirmation with critical thinking and empowerment, to increase reasoning skill, problem solving capacity, self-protective behavior change, and well-being which facilitates the reduction of risky sexual behaviors. A convenience sample of 438 AAMSM will be recruited to participate in the study. We anticipate recruiting potential participants for the CTCA RCT through a variety of community venues, using both active (i.e., venue outreach) and passive (i.e., referral, flyers/handcards, Internet) recruitment techniques. The intervention will be evaluated using baseline, 3-month and 6-month follow up assessments. This project will also conduct exit surveys to identify men who were more favorable—men who agreed with positive comments about the intervention and those who were less favorable—men who disagreed with positive comments about the intervention. Exit interviews will be conducted with 15 favorable and 15 less favorable men identified by the Exit Survey to help understand participants' experiences with the CTCA intervention and their thoughts about the content of the intervention and ways in which it could be improved. Using the participant responses to the exit survey, we will categorize participants into two categories: favorable (those men reporting a favorable reaction to the intervention) and unfavorable (those men reporting an unfavorable reaction to the intervention). Once we have 50 participants in each category, we will randomly select 15 participants from each group and invite them to participate in the exit interview. We anticipate that we will need to repeat these procedures and extend an invitation to at least 65 participants in order to reach and successfully interview 15 participants in each group.

CDC is requesting approval for a 3-year clearance for data collection. Data collection will begin November 2012 and end January 2015. The data collection system involves a pre and full screening, brief locator information, record locator information, baseline assessment, 3-month follow-up assessment, 6-month follow-up assessment, participant evaluation forms, exit survey, and exit interviews. An estimated 700 men will be pre-screened and 500 will be full-screened for eligibility in order to enroll 438 men. The baseline and follow-up questionnaires will be administered electronically using audio computer assisted self-interview (ACASI). The ACASI interview includes questions about participants' socio-demographic information, health and healthcare, sexual activity, substance use, and other psychosocial issues. The duration of each baseline, 3-month, and 6-month assessment is estimated to be 60 minutes; the exit survey 10 minutes; the exit interview 30 minutes; pre-screening form 5 minutes; full-screening form 10 minutes; brief locator information form 5 minutes; record locator information form 10 minutes; each participant evaluation survey 5 minutes.

There is no cost to participants other than their time.

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per respondent (in hours)	Total annual burden in hours
Prospective Study Participant	Pre-Screening Form	700	1	5/60	58
Prospective Study Participant	Full-Screening Form	515	1	10/60	86
Prospective Study Participant	Brief Locator Form	515	1	5/60	43
Enrolled Study Participant	Record Locator Form	438	1	10/60	73
Enrolled Study Participant	Baseline Assessment	438	1	1	438
Enrolled Study Participant	3-month Follow-up Assessment	395	1	1	395
Enrolled Study Participant	6-month Follow-up Assessment	350	1	1	350
Enrolled Study Participant	Participant Evaluation Forms	438	6	5/60	219
Enrolled Study Participant	Exit Survey	350	1	10/60	58
Enrolled Study Participant	Exit Interview	30	1	30/60	15

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per respondent (in hours)	Total annual burden in hours
Total					1735

Kimberly S. Lane,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2012–4566 Filed 2–27–12; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0171]

Using Innovative Technologies and Other Conditions of Safe Use To Expand Which Drug Products Can Be Considered Nonprescription; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The U.S. Food and Drug Administration (FDA or the Agency) is announcing a public hearing to obtain input on a new paradigm we are considering. Under this paradigm, the Agency would approve certain drugs that would otherwise require a prescription for nonprescription use (also known as over-the-counter or OTC) under conditions of safe use. These conditions of safe use would be specific to the drug product and might require sale in certain pre-defined health care settings, such as a pharmacy. This public hearing is being held to obtain information and comments from the public on the feasibility of this paradigm and its potential benefits and costs.

DATES: *Public Hearing:* The public hearing will be held on March 22 and 23, 2012, from 9 a.m. to 4 p.m. The meeting may be extended or may end early depending on the level of public participation.

Presentations and Comments: Submit either electronic or written requests for oral presentations and comments by March 9, 2012. (See section IV of this document for details.) Either electronic or written comments will be accepted after the hearing until May 7, 2012 (See section VI of this document for details.)

ADDRESSES: The public hearing will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503, Silver Spring, MD, 20993–0002.

Comments and Transcripts: Submit either electronic or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* All comments should be identified with the docket number found in brackets in the heading of this document. Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 45 days after the hearing.

FOR FURTHER INFORMATION CONTACT: Lee Lemley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903–0002, 301–796–3441, Fax: 301–847–8753, email: *OTCTechnologiesPublicMeeting@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing a public hearing to obtain input on a potential new paradigm under which the Agency would approve certain drugs that would otherwise require a prescription for nonprescription use under conditions of safe use specific to the drug product. Some drugs approved in this manner might require sale in certain pre-defined health care settings, such as a pharmacy.

I. Background

A. Prescription and Nonprescription Drugs

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA approves new drugs under section 505 (21 U.S.C. 355) either as prescription or nonprescription. Under section 503(b)(1)(A) of the FD&C Act (21 U.S.C. 353(b)(1)(A)), a drug must be dispensed by prescription if, ''because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.'' Under sections 505(d)(1) and (d)(4), FDA has considerable latitude in determining whether the information submitted as part of a new drug application (NDA) is sufficient to ensure that a drug is safe for use under its proposed labeling. FDA also makes a determination under 503(b) as to whether the product meets the criteria for prescription-only dispensing.

Prescription drugs are dispensed upon receipt of a prescription from a practitioner licensed by law to administer the drug (which may include health care professionals such as physicians, nurse practitioners, physician's assistants, and others whom we will refer to here as practitioners or prescribers). (See 21 U.S.C. 353(b).) In many instances, under the current regulatory system, a patient has to obtain at least the initial prescription, and in some cases, prescription refills, from a practitioner through an in person interaction. Obtaining a refill for other prescription drugs involves at least a telephone call or other communication with the practitioner. In contrast, nonprescription drugs (sometimes referred to as over-the-counter or OTC products) can be purchased by consumers in pharmacies, supermarkets, and other retail establishments without the need for a prescription. Currently, consumers can purchase nonprescription drugs from a retailer for diseases or conditions that do not meet the statutory criteria for prescription products and that are safe and effective for use in self-medication as directed in the labeling. (See 21 U.S.C. 353(b).) Generally, OTC products: (1) Are available to treat diseases or conditions that can be self-diagnosed without a prior interaction with a practitioner, (2) are not associated with toxicities that require an evaluation of the benefits and risks by a practitioner; and (3) do not require a practitioner's input for use.

B. Undertreatment of Diseases and Other Effects on the Health Care System

Undertreatment of many common diseases or conditions in the United States is a well recognized public health problem. Increasing the number of people who are able to obtain for the first time and those who continue on necessary drug therapy could provide improved health outcomes. The requirement to obtain a prescription for appropriate medication (and to make one or more visits to a practitioner) may contribute to undertreatment of certain common medical conditions including