FEDERAL RESERVE SYSTEM

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

The notices, offers, statements, and comments 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 January 2, 2014.

A. Federal Reserve Bank of Chicago
   (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:
   1. The George Breckenridge Family Trust, with Maureen Breckenridge as trustee, and Maureen Breckenridge as trustee of the George Breckenridge Family Trust and the Maureen Breckenridge Trust, individually, and the George Breckenridge Family Trust, the Maureen Breckenridge Trust, and Maureen Breckenridge as trustee of the George Breckenridge Family Trust and the Maureen Breckenridge Trust, all of Yates City, Illinois, together as a group acting in concert, to retain voting shares of Community Bank, Albia, Iowa, and thereby indirectly retain voting shares of Community Bank Shares, Inc., and thereby indirectly retain voting shares of First Valley Bank, Albia, Iowa.

B. Federal Reserve Bank of Kansas City
   (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:
   1. Jay R. Trofholz, Columbus, Nebraska, to retain voting shares of Valley Bank Shares, Inc., and thereby indirectly retain voting shares of First Nebraska Bank, both in Valley, Nebraska, to retain voting shares of First Nebraska Bank Shares, Inc., and thereby indirectly retain voting shares of Nebraska, to retain voting shares of City, Missouri 64198–0001:

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 to the Reserve Bank indicated for that notice or to the offices of the Board of Governors who 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.

A. Federal Reserve Bank of Chicago
   (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:
   1. Van Buren Bancorporation ESOP, Keosauqua, Iowa; to acquire at least an additional 6 percent, for a total of 50.1 percent of the voting shares of Van Buren Bancorporation, Keosauqua, Iowa, and thereby indirectly acquire additional voting shares of Community First Bank, Keosauqua, Iowa, and First Iowa State Bank, Albia, Iowa.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Opportunity for Co-Sponsorship of the President’s Challenge Physical Activity and Fitness Awards Program

AGENCY: President’s Council on Fitness, Sports, and Nutrition, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The President’s Council on Fitness, Sports, and Nutrition (PCFSN) announces the opportunity for non-federal public and private sector entities to co-sponsor and administer a series of financially self-sustaining activities related to the President’s Challenge Physical Activity and Fitness Awards Program (President’s Challenge). Potential co-sponsors must have a demonstrated interest in and be capable of managing the day-to-day operations associated with the program and be willing to participate substantively in the co-sponsored activity.

DATES: To receive consideration, a request to participate as a co-sponsor must be received by 5:00 p.m. EST on Friday, January 31, 2014, at the address listed. Requests will meet the deadline if they are either (1) received on or before the deadline; or (2) postmarked on or before the deadline. Private metered postmarks will not be accepted as proof of timely mailing. Hand-delivered requests must be received by 5:00 p.m. e.s.t. Requests that are received after the deadline date will be returned to the sender.

ADDRESSES: Proposals for co-sponsorship should be sent to Yesenia Díaz, Public Health Advisor, President’s Council on Fitness, Sports, and Nutrition, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852; Telephone: (240) 276–9865, Fax: (240) 276–9860. Proposals may also be submitted via email to: Yesenia.diaz@hhs.gov.

FOR FURTHER INFORMATION CONTACT: Yesenia Díaz, Public Health Advisor, President’s Council on Fitness, Sports, and Nutrition, Telephone: (240) 276–9865, email: Yesenia.diaz@hhs.gov.

SUPPLEMENTARY INFORMATION:
Background

PCFSN was originally established as the President’s Council on Youth Fitness by President Dwight D. Eisenhower in 1956. In 2010, President Barack Obama issued Executive Order (EO) 13545, dated June 22, 2010, to amend EO 13265, dated June 6, 2002. EO 13545 changed the organization’s name from the President’s Council on Physical Fitness and Sports (PCPFS) to the President’s Council on Fitness, Sports, and Nutrition (PCFSN); expanded the mission of the Council to include nutrition; and, increased the maximum number of members who serve on the Council from 20 to 25.

The Council advises the President, through the Secretary of Health and Human Services, about the challenges and opportunities to promote fitness, sports and nutrition across the United States. Specifically, the Council, as outlined in EO 13265, Section (3)(b), is directed to “advise the Secretary on ways to promote regular physical activity, fitness, sports participation, and good nutrition. Recommendations may address, but are not necessarily limited to, public awareness campaigns; federal, state and local physical activity; fitness, sports participation, and nutrition initiatives; and partnership opportunities between public- and private-sector health-promotion entities.” Section (3)(c) adds, “The Council shall function as a liaison to relevant state, local, and private entities in order to advise the Secretary regarding opportunities to extend and improve physical activity, fitness, sports, and nutrition programs and services at the local, state, and national levels.” In addition, the Council, as stated in Section (3)(d) “shall monitor the need to enhance programs and educational and promotional materials sponsored, overseen, or disseminated by the Council, and shall advise the Secretary as necessary concerning such need.” The EO also states in Section (1) that in implementing this order, the “Secretary shall be guided by the science-based federal Dietary Guidelines for Americans and the Physical Activity Guidelines for Americans.” Through the authority of section 1704 of the Public Health Service Act, PCFSN may support and “encourage others to support” activities related to health information and promotion, including the publication of information and securing the cooperation of communication media.

The purpose of the President’s Challenge is to motivate individuals six years of age and older to start and maintain a regular program of physical activity and good nutrition leading to improved health and fitness. Since its inception in 1966, the program has reached millions of American youth. In 2002, the program expanded to include adults aged 18 and older. Program materials are available in English and Spanish.

Requirements of Co-Sponsorship: PCFSN is seeking a co-sponsoring organization capable of managing the development and distribution of program awards and materials, responding to program inquiries, administering program Web sites, and identifying ways to enhance the program and participation. This co-sponsorship agreement will be in place for a period of four years beginning on September 1, 2014.

Awards Programs

A. Presidential Active Lifestyle Award (PALA+): Recognizing individuals aged six and older for being physically active and adopting healthy eating habits on a regular basis. Participants are encouraged to track their participation using an interactive web-based physical activity tracker or a paper log.

B. Presidential Champions: A web-based points program for individuals aged six and older. This program allows individuals to earn points based on the amount of daily of physical activity tracked. With an unlimited amount of time, individuals can earn different awards based on their levels of physical activity in the program. Awards included in this program: Platinum, Gold, Silver, and Bronze Awards.

C. Presidential Youth Fitness Program: The Presidential Youth Fitness Program provides a model for fitness education within a comprehensive, quality physical education program. The program provides resources and tools for physical educators to enhance their fitness education process. The Presidential Youth Fitness Program has replaced the President’s Challenge Physical Fitness Test to emphasize the role of schools in promoting the health and well-being of ALL students.

D. Adult Fitness Test: A web-based test for adults aged 18 and older. No awards are currently linked to this test.

Distribution Center

Each of these program areas shall involve the promotion and distribution of award items. These items may include, but are not limited to, emblems, medallions, ribbons, lapel pins, certificates, bumper stickers, magnets, pedometers, and apparel. Participating organizations and individuals purchase awards and other program materials directly from the administering organization for a nominal fee. This program is designed to be financially self-sustaining.

Web Site Administration

Administration of the President’s Challenge Program Web sites (www.pyfp.org, www.presidentschallenge.org, and www.adultfitnesstest.org) shall consist of, but not be limited to, the following: hosting, maintenance, and customer service for an online order center as well as a listserv. Additionally, the co-sponsoring organization shall manage the President’s Challenge Advocate onboarding process and database with approval from PCFSN. All work performed in association with these Web sites shall be consistent with Section 508 compliance requirements.

Additional Roles and Responsibilities

The co-sponsoring organization shall help promote the program through outreach activities which may include: Exhibiting at conferences, speaking at events, and using social media. The co-sponsoring organization shall identify and recommend ways to enhance the program experience, delivery, and outreach.

Eligibility for Co-Sponsorship: To be eligible, a requestor shall: (1) Have a demonstrated interest and understanding of physical activity, physical fitness, sports, and nutrition; (2) participate substantively in the co-sponsored activity (not just provide funding or logistical support); (3) have an organizational or corporate mission that is consistent with the public health and safety mission of the Department of Health and Human Services; and (4) agree to sign a co-sponsorship agreement with PCFSN which will set forth the details of the co-sponsored activity including the requirements such that any fees raised should not be designed to exceed the co-sponsor’s costs, and fees collected by the co-sponsor shall be limited to the amount necessary to cover the co-sponsor’s related operating expenses.

The organization selected shall furnish the necessary personnel, materials, services, and facilities to administer the President’s Challenge program, including the purchase and/or production of all program and award materials; distribution of program and award materials; promotion and statistical evaluation of the program; quarterly and annual budget and demographic reports; maintenance of partnership list; and other administrative duties. These duties will
be determined in a Memorandum of Agreement and an annual plan.

Co-Sponsorship Proposal: Each co-sponsorship proposal shall contain a description of: (1) The entity or organization; (2) its background in promoting physical activity, physical fitness, sports, and nutrition; (3) its proposed involvement in the co-sponsored activity; and (4) plan for implementation with a timeline.

Evaluation Criteria: PCFSN will select the co-sponsor using the following evaluation criteria:

(1) Requestor’s qualifications and capability to fulfill co-sponsorship responsibilities;
(2) Requestor’s creativity related to enhancing the program, including the medium through which program messages are delivered and ideas for improving program offerings;
(3) Requestor’s potential for reaching underserved/special populations;
(4) Requestor’s experience administering national awards programs;
(5) Requestor’s past or current work specific to national programs or projects in the area(s) of physical activity, physical fitness, sports, and nutrition among individuals and in schools and organizations;
(6) Requestor’s personnel: name, professional qualifications and specific expertise of key personnel who would be available to work on these projects;
(7) Requestor’s facilities: availability and description of facilities required to administer the program including office space and information technology and telecommunication resources;
(8) Requestor’s description of financial management: discussion of experience in developing an annual budget and collecting and managing monies from organizations and individuals; and
(9) Requestor’s proposed plan for managing PCFSN awards programs, including such financial aspects as Web site development and/or enhancement, cost of program materials, and distribution of those items.

Availability of Funds: There are no federal funds available for this co-sponsorship.


Shellie Y. Pfohl,
Executive Director, President’s Council on Fitness, Sports, and Nutrition, U.S. Department of Health and Human Services.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2013–N–0001]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA’s regulatory issues.

Date and Time: The meeting will be held on January 15, 2014, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, The Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: http://www.fda.gov/AdvisoryCommittees/default.htm; under the heading “Resources for You,” click on “Public Meetings at the FDA White Oak Campus.” Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: CRDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at http://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 204886, vorapaxar sulfate, proposed trade name ZONTIVITY, 2.5 milligram tablets, submitted by Merck Sharp & Dohme Corp., Inc., for the proposed indication of reduction of atherothrombotic events in patients with a history of myocardial infarction (MI). The applicant also proposes that ZONTIVITY has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 9, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 3, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Those persons selected will notify interested persons regarding their request to speak by January 6, 2014.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristina Toliver at least 7 days in advance of the meeting.