after the meeting. This ComE–IN meeting will be Webcast live via the Internet at: *http://fdic.windrosemedia.com.* Questions or troubleshooting help can be found at the same link. For optimal viewing, a high speed internet connection is recommended. The ComE–IN meeting videos are made available on-demand approximately two weeks after the event.

Dated: September 30, 2016.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary, Federal Deposit Insurance Corporation.*

[FR Doc. 2016–24039 Filed 10–4–16; 8:45 am]

**BILLING CODE 6714–01–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 October 31, 2016.

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

1. *Caldwell Holding Company,* Columbia, Louisiana; to acquire Progressive National Financial Corporation, and thereby indirectly acquire Progressive National Bank, both in Mansfield, Louisiana.

Board of Governors of the Federal Reserve System, September 30, 2016.

**Margaret McCloskey Shanks,**

*Deputy Secretary of the Board.*

[FR Doc. 2016–24055 Filed 10–4–16; 8:45 am]

**BILLING CODE 6210–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–0001]**

### Pharmacy Compounding Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmacy Compounding Advisory Committee (PCAC). The general function of the committee is to provide advice on scientific, technical, and medical issues concerning drug compounding, as well as any other product for which FDA has regulatory responsibility, and to make appropriate recommendations to the Agency. The meeting will be open to the public.

**DATES:** The meeting will be held on November 3, 2016, from 8:30 a.m. to 4:30 p.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

**FOR FURTHER INFORMATION CONTACT:** Cindy Hong, 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, *PCAC@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.

*Background:* Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or licensed physician, to be exempt from the following three sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act): (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) concerning current good manufacturing practice (CGMP); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) concerning the labeling of drugs with adequate directions for use; and (3) section 505 (21 U.S.C. 355) concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs).

The Drug Quality and Security Act added a new section 503B to the FD&C Act (21 U.S.C. 353b), which created a new category of compounders termed ''outsourcing facilities.'' Under section 503B of the FD&C Act, outsourcing facilities are defined, in part, as facilities that meet certain conditions described in section 503B, including registration with FDA as an outsourcing facility. If these conditions are satisfied, a drug product compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1) concerning the labeling of drugs with adequate directions for use); (2) section 505 concerning the approval of human drug products under NDAs or ANDAs; and (3) section 582 concerning the drug supply chain security requirements (21 U.S.C. 360eee–1). Outsourcing facilities are not exempt from CGMP requirements in section 501(a)(2)(B).

One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that a bulk drug substance (active pharmaceutical ingredient) used in a compounded drug product must meet one of the following criteria: (1) Complies with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable