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 September 21, 2017.

A. Federal Reserve Bank of Atlanta
(Kathryn Haney, Director of Applications) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to Applications.Comments@atl.frb.org.

B. Federal Reserve Bank of Kansas City
(Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. Stockmens Limited Partnership, Rapid City, South Dakota; to engage in investment advisory services, by acquiring a 24 percent interest in Rock Creek Advisors, LLC, Rapid City, South Dakota, and thereby engage in investment advisory services pursuant to section 225.28(b)(6) of Regulation Y.

2. Ann Misback, Secretary of the Board.

The notices also will be available for inspection at the Federal Reserve Bank indicated.

B. Federal Reserve Bank of Kansas City
(Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. Stockmens Limited Partnership, Rapid City, South Dakota; to engage in investment advisory services, by acquiring a 24 percent interest in Rock Creek Advisors, LLC, Rapid City, South Dakota, and thereby engage in investment advisory services pursuant to section 225.28(b)(6) of Regulation Y.

2. Ann Misback, Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Delegation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled “Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR part 1271; Guidance for Industry.” The guidance document provides establishments that manufacture non-reproductive human cells, tissues, and cellular and tissue-based products (HCT/Ps), regulated solely under the Public Health Service Act (PHS Act) and under FDA regulations, with recommendations and relevant examples for complying with the requirements to investigate and report HCT/P deviations. The guidance announced in this notice finalizes the draft guidance of the same title dated December 2015.

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”