

**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](mailto:Applications.Comments@atl.frb.org):

1. *Joseph Huntley Johnson III, Birmingham, Alabama, Lawrence Harris Johnson, Birmingham, Alabama, and James Hughes Johnson, Tuscaloosa, Alabama*; to become part of the Johnson Family Control Group and thereby retain voting shares of SNB Holdings, Inc., Slocomb, Alabama, and its subsidiary Friend Bank, Slocomb, Alabama.

Board of Governors of the Federal Reserve System, September 1, 2017.

**Ann Misback,**

*Secretary of the Board.*

[FR Doc. 2017-19006 Filed 9-6-17; 8:45 am]

**BILLING CODE 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 applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 21, 2017.

*A. 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.

Board of Governors of the Federal Reserve System, September 1, 2017.

**Ann Misback,**

*Secretary of the Board.*

[FR Doc. 2017-19007 Filed 9-6-17; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2015-D-4386]

**Deviation 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."

*Instructions:* All submissions received must include the Docket No. FDA-2015-D-4386 for "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.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section

for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Tami Belouin, 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 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 document provides establishments that manufacture HCT/Ps, regulated solely under section 361 of the PHS Act and the regulations under 21 CFR part 1271, with recommendations and relevant examples for complying with the requirements under 21 CFR 1271.350(b) to investigate and report HCT/P deviations. The examples provided in the guidance are intended to illustrate those HCT/P deviations that have been most frequently reported to FDA, CBER.

The guidance does not apply to reproductive HCT/Ps or to HCT/Ps regulated under 21 CFR part 1270 and recovered before May 25, 2005. The guidance does not apply to healthcare professionals who implant, transplant, infuse, or transfer HCT/Ps into recipients. The guidance also does not apply to HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, nor does it apply to investigational HCT/Ps subject to an investigational new drug application or an investigational device exemption.

In the **Federal Register** of December 24, 2015 (80 FR 80364), FDA announced the availability of the draft guidance of the same title dated December 2015. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes additional examples and editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated December 2015.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “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.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

**II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 1271 have been approved under OMB control number 0910-0543.

**III. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: August 23, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-18737 Filed 9-6-17; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Notice of Listing of Members of the National Institutes of Health’s Senior Executive Service 2017 Performance Review Board (PRB)**

**SUMMARY:** The National Institutes of Health (NIH) announces the persons who will serve on the National Institutes of Health’s Senior Executive Service 2017 Performance Review Board.

**FOR FURTHER INFORMATION CONTACT:** For further information about the NIH Performance Review Board, contact the Office of Human Resources, Division of Senior and Scientific Executive Management, National Institutes of Health, Building 2, Room 5E18, Bethesda, Maryland 20892, telephone 301-402-7999 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:** This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure