Board of Governors of the Federal Reserve System, March 10, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–05173 Filed 3–12–20; 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, if any, 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)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th and Constitution Avenue NW, Washington, DC 20551–0001, not later than April 13, 2020.

A. Federal Reserve Bank of St. Louis (David L. Hubbard, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *BankFirst Capital Corporation, Macon, Mississippi;* to acquire Traders & Farmers Bancshares, Inc., and thereby indirectly acquire Traders & Farmers Bank, both of Haleyville, Alabama.

Board of Governors of the Federal Reserve System, March 9, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–05101 Filed 3–12–20; 8:45 am]

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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 10 of the Home Owners' Loan Act (12 U.S.C. 1467a) (HOLA) and Regulation LL (12 CFR part 238) 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 § 238.53 of Regulation LL (12 CFR 238.53). Unless otherwise noted, these activities will be conducted throughout the United States.

Each application is available for inspection at the Federal Reserve Bank indicated. The application 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 10(c)(4)(B) of HOLA (12 U.S.C. 1467a(c)(4)(B)).

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than March 30, 2020.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *MidCountry Acquisition Corp., Minneapolis, Minnesota;* to engage in nonbanking activities pursuant to sections 238.53(b)(2) and (b)(3) of Regulation LL through the formation of CB Shared Services, Inc., Minneapolis, Minnesota, which will provide information technology, human resources, Call Report preparation, and compliance services to MidCountry Bank, Bloomington, Minnesota, and other subsidiary banks of holding company affiliates.

Board of Governors of the Federal Reserve System, March 9, 2020.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2020–05102 Filed 3–12–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Circulatory System Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on April 16, 2020, from 8 a.m. to 6 p.m.

ADDRESSES: Doubletree by Hilton Washington, DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900. The hotel's website is at: *https://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-washington-dc-north-gaithersburg-GAIGWDT/index.html.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Aden Asefa, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5214, Silver Spring, MD 20993–0002, *Aden.Asefa@fda.hhs.gov,* 301–796–0400, 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 website at *https://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.

SUPPLEMENTARY INFORMATION:

Agenda: On April 16, 2020, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the TransMedics Organ Care System (OCS)—Heart, by TransMedics, Inc. The proposed Indication for Use for the TransMedics OCS—Heart, as stated in the PMA, is as follows:

The TransMedics Organ Care System (OCS) Heart System is a portable ex-vivo organ perfusion and monitoring system indicated for the resuscitation, preservation, and assessment of donor hearts with one or more of the following characteristics for transplantation into a potential recipient in a near-physiologic, normothermic, and beating state:

- Expected cross-clamp or ischemic time ≥4 hours due to donor or recipient characteristics (*e.g.,* donor-recipient geographical distance, expected recipient surgical time)
- Donor age ≥55 years
- Donors with history cardiac arrest and downtime ≥20 minutes
- Donor history of alcohol use
- Donor LV ejection fraction (LVEF) ≤50% but ≥40%
- Donor history of left ventricular hypertrophy (septal or posterior wall thickness of >12 ≤16 mm)

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 website 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 website after the meeting. Background material is available at *https://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 April 9, 2020. Oral presentations from the public will be scheduled on April 16, 2020, 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 April 1, 2020. 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. The contact person will notify interested persons regarding their request to speak by April 2, 2020.

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 disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05132 Filed 3–12–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2001–D–0007 (formerly Docket No. 2001D–0221)]

Biological Product Deviation Reporting for Blood and Plasma Establishments; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a revised final guidance entitled ''Biological Product Deviation Reporting for Blood and Plasma Establishments; Guidance for Industry.'' The final guidance document provides blood and plasma establishments with revised recommendations related to biological product deviation (BPD) reporting. The guidance is intended to assist blood and plasma establishments in determining when a report is required, who submits the report, what information to submit in the report, the timeframe for reporting, and how to submit the report. The revised guidance explains that we do not consider post donation information (PDI) events to require BPD reports. The revised guidance also contains other technical updates and editorial revisions to improve clarity and provide a more streamlined document. For the purposes of this guidance, ''blood and plasma establishment'' includes licensed manufacturers of blood and blood components, including Source Plasma, unlicensed registered blood establishments, and transfusion services. The guidance announced in this notice supersedes the document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments,'' dated October 2006.

DATES: The Agency is soliciting public comment, but is implementing this guidance immediately, because the Agency has determined that prior public participation is not feasible or appropriate. Submit either electronic or written comments on Agency guidances at any time. The announcement of the guidance is published in the **Federal Register** on March 13, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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