

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 July 24, 2017.

*A. Federal Reserve Bank of Chicago* (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Scott Michael Rasmussen*, Germantown, Wisconsin; as trustee under a 2017 Voting Agreement, to acquire voting shares of Waupaca Bancorporation, Inc., and thereby indirectly acquire shares of First National Bank, both of Waupaca, Wisconsin.

*B. Federal Reserve Bank of Minneapolis* (Brendan S. Murrin, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Nancy J. Petersen*, Bismarck, North Dakota; to individually acquire voting shares of Cornerstone Holding Company, Inc., Fargo, North Dakota, and thereby indirectly acquire voting shares of Cornerstone Bank, Fargo, North Dakota.

Board of Governors of the Federal Reserve System, July 6, 2017.

**Yao-Chin Chao**,

*Assistant Secretary of the Board.*

[FR Doc. 2017-14506 Filed 7-10-17; 8:45 am]

**BILLING CODE 6210-01-P**

## 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 July 26, 2017.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Nancy J. Petersen*, Bismarck, North Dakota; to individually retain voting shares of Cornerstone Holding Company, Inc., Fargo, North Dakota, and thereby indirectly retain shares of Cornerstone Bank, Fargo, North Dakota.

Board of Governors of the Federal Reserve System, July 5, 2017.

**Yao-Chin Chao**,

*Assistant Secretary of the Board.*

[FR Doc. 2017-14435 Filed 7-10-17; 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, 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 August 3, 2017.

*A. Federal Reserve Bank of Atlanta* (Chapelle Davis, Assistant Vice President) 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. *BOLC Corp*; to become a bank holding company by acquiring 100

percent of the outstanding voting shares of Bank of Lincoln County, both of Fayetteville, Tennessee.

Board of Governors of the Federal Reserve System, July 6, 2017.

**Yao-Chin Chao**,

*Assistant Secretary of the Board.*

[FR Doc. 2017-14507 Filed 7-10-17; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2015-E-4727 and FDA-2015-E-4615]

### Determination of Regulatory Review Period for Purposes of Patent Extension; Intercept Blood System for Plasma

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for INTERCEPT BLOOD SYSTEM FOR PLASMA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

**DATES:** Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by September 11, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 8, 2018. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 11, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of September 11, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery

service acceptance receipt is on or before that date.

#### 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 Nos. FDA-2015-E-4727 and FDA-2015-E-4615 for "Determination of Regulatory Review Period for Purposes of Patent Extension; INTERCEPT BLOOD SYSTEM FOR PLASMA." Received comments, those filed in a timely manner (see **ADDRESSES**), 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 and 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.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis

for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device INTERCEPT BLOOD SYSTEM FOR PLASMA. INTERCEPT BLOOD SYSTEM FOR PLASMA is indicated for inactivation of bacterial and viral contaminants in Fresh Frozen Plasma prior to transfusion. Subsequent to this approval, the USPTO received patent term restoration applications for INTERCEPT BLOOD SYSTEM FOR PLASMA (U.S. Patent Nos. 5,593,823 and 6,951,713) from Cerus Corporation, and the USPTO requested FDA's assistance in determining this patents' eligibility for patent term restoration. In a letter dated April 26, 2016, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of INTERCEPT BLOOD SYSTEM FOR PLASMA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

##### II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for INTERCEPT BLOOD SYSTEM FOR PLASMA is 6,497 days. Of this time, 6,114 days occurred during the testing phase of the regulatory review period, while 383 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* March 5, 1997. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for

human tests to begin became effective on March 10, 1997. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on March 5, 1997, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the biological device under section 515 of the FD&C Act (21 U.S.C. 360e):* November 29, 2013. The applicant claims December 23, 2013, as the date the premarket approval application (PMA) for INTERCEPT BLOOD SYSTEM FOR PLASMA (PMA BP130076) was initially submitted. However, FDA records indicate that the complete PMA BP130076 was submitted on November 29, 2013.

3. *The date the application was approved:* December 16, 2014. FDA has verified the applicant's claim that PMA BP130076 was approved on December 16, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,860 days or 5 years of patent term extension.

### III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in 21 CFR 60.30, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (see **ADDRESSES**).

Dated: July 5, 2017.

**Anna K. Abram,**

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

[FR Doc. 2017–14454 Filed 7–10–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–N–1129]

#### Medical Devices; Exemptions From Premarket Notification: Class II Devices

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing a list of class II devices that the Agency has determined based on established factors to no longer require premarket notification to provide reasonable assurance of safety and effectiveness, subject to certain limitations. FDA is publishing this notice of that determination in accordance with procedures established by the 21st Century Cures Act. This notice represents FDA's final determination with respect to the list of class II devices proposed in a March 14, 2017, **Federal Register** document. The exemptions in this notice will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations.

#### FOR FURTHER INFORMATION CONTACT:

Bryce Bennett, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5244, Silver Spring, MD 20993, email: [Gregory.Bennett@fda.hhs.gov](mailto:Gregory.Bennett@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of March 14, 2017 (82 FR 13609), FDA issued a notice proposing to exempt a list of class II devices from the premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)), subject to certain limitations. This notice was issued in accordance with the 21st Century Cures Act (Pub. L. 114–255), which was signed into law on December 13, 2016. Section 3054 of that statute amended section 510(m) of the FD&C Act. As amended, section 510(m)(1)(A) of the FD&C Act provides that, within 90 days after enactment of the 21st Century Cures Act and at least once every 5 years thereafter, FDA must publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of

the FD&C Act (generally referred to as a premarket notification or “510(k)”) to provide reasonable assurance of safety and effectiveness. Within 210 days of enactment of the 21st Century Cures Act, FDA must publish in the **Federal Register** a list representing its final determination regarding the list of devices proposed in the March 14, 2017, notice. Section 510(m)(3) of the FD&C Act provides that upon the date that this final list is published in the **Federal Register**, a 510(k) will no longer be required for the listed devices and the applicable classification regulation for these devices shall be deemed amended to incorporate such exemption. Interested persons were given until May 15, 2017, to comment on the proposed list of class II devices. After reviewing these comments and considering whether the proposed list should be modified, FDA is now identifying its final determination as to which of those devices are now exempt from premarket notification requirements, subject to certain limitations, as indicated in tables 1 to 3 of this notice.

In a future action, FDA intends to amend the codified language for each listed device's classification regulation to reflect this final determination. Persons with pending 510(k) submissions for devices that are now exempt from premarket notification, subject to the limitations on exemptions, should withdraw their submissions.

These exemptions will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with Federal regulation. Specifically, regulated industry will no longer have to invest time and resources in premarket notifications, including preparation of documents and data for submission to FDA, payment of user fees associated with 510(k) submissions, and responding to questions and requests for additional information from FDA during 510(k) review.

##### II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff” (“Class II 510(k) Exemption Guidance”) (Ref. 1).