

Respondents: Business or other for-profit, not-for-profit institutions, and state, local or tribal government.

Number of Respondents and Responses: 3,788 respondents; 3,788 responses.

Estimated Time per Response: .25 minutes.

Frequency of Response: One time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 308(b).

Total Annual Burden: 947 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: No questions of a confidential nature are asked.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget during this comment period under delegated authority. The Commission inadvertently published a regular notice rather than a delegated notice announcing submission of this information collection at the end of the 60 day comment period which was March 29, 2010 (75 FR 4077, January 26, 2010). Therefore, the Commission is required to publish a 30 day notice following a regular notice. The Commission is reporting no change to the reporting requirement. However, there is a 1,436 hour reduction adjustment to the total annual burden hours since the last submission to the OMB in 2007. This reduction is due to 5,743 fewer respondents.

This rule section requires that affected applicants to submit a list of any radio facilities they hold within 40 miles of the base station transmitter site being applied for. This information is used to determine if an applicant's proposed system is necessary in light of communications facilities it already owns. Such a determination helps the Commission to equitably distribute limited spectrum and prevents spectrum warehousing. The information is collected only once – upon initial license application.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary,*

*Office of the Secretary,*

*Office of Managing Director.*

[FR Doc. 2010-7557 Filed 4-2-10; 8:45 am]

**BILLING CODE 6712-01-S**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisition of Shares of Bank or Bank Holding Companies

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 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 office 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 April 19, 2010.

*A. Federal Reserve Bank of Richmond* (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *David Muldrow Beasley, Society Hill, South Carolina*, individually and as a member of a group acting in concert including Henry Wesley Beasley, Richard Lewis Beasley, both of Florence, South Carolina, and Richard Lee Beasley, Society Hill, South Carolina, to retain control of First Carolina Bancshares Corporation, Darlington, South Carolina, and thereby indirectly retain control of Carolina Bank and Trust Company, Lamar, South Carolina.

Board of Governors of the Federal Reserve System, March 31, 2010.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2010-7613 Filed 4-2-10; 8:45 am]

**BILLING CODE 6210-01-S**

## 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 also will 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. Additional information on all bank holding companies may be obtained from the National Information Center website at [www.ffiec.gov/nic/](http://www.ffiec.gov/nic/).

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 April 28, 2010.

*A. Federal Reserve Bank of New York* (Anne MacEwen, Bank Applications Officer) 33 Liberty Street, New York, New York 10045-0001:

1. *The Goldman Sachs Group, Inc., New York, New York*, to acquire up to 24.9 percent of SKBHC Holdings LLC, Corona del Mar, California, which is applying to become a bank holding company, and thereby indirectly acquire Starbuck Bancshares, Inc. and The First National Bank of Starbuck, both of Starbuck, Minnesota.

Board of Governors of the Federal Reserve System, March 31, 2010.

**Robert deV. Frierson,**

*Deputy Secretary of the Board.*

[FR Doc. 2010-7614 Filed 4-2-10; 8:45 am]

**BILLING CODE 6210-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2009-E-0202 and FDA-2009-E-0204]

### Determination of Regulatory Review Period for Purposes of Patent Extension; LUSEDRA

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for

LUSEDRA 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 Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, 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 human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product LUSEDRA (fospropofol disodium). LUSEDRA is a sedative-hypnotic agent indicated for monitored anesthesia care sedation in

adult patients undergoing diagnostic or therapeutic procedures. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for LUSEDRA (U.S. Patent Nos. 6,204,257 and 6,872,838) from University of Kansas, and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LUSEDRA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LUSEDRA is 2,405 days. Of this time, 1,962 days occurred during the testing phase of the regulatory review period, while 443 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* May 15, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 15, 2002.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* September 27, 2007. FDA has verified the applicant's claim that the new drug application (NDA) 22-244 was submitted on September 27, 2007.

3. *The date the application was approved:* December 12, 2008. FDA has verified the applicant's claim that NDA 22-244 was approved on December 12, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,424 days of patent term extension for patent no. 6,204,257 and 899 days of patent term extension for patent no. 6,872,838.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 4, 2010. 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 October 4, 2010. To meet its burden, the petition must 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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 22, 2010.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

[FR Doc. 2010-7516 Filed 4-2-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0495]

#### Draft Guidance for Industry and Food and Drug Administration Staff; Medical Devices; Neurological and Physical Medicine Device Guidance Documents; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of draft special controls guidance documents for 11 neurological and physical medicine devices. FDA has developed a draft special controls guidance document for each of the 11 devices. These draft guidance documents describe a means by which these devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that would designate special controls for each of these devices and would exempt six of them from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the act). These draft guidance documents are not final nor are they in effect at this time.

**DATES:** Although you can comment on any guidance documents at any time