

Federal Communications Commission

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Deputy Chief, Auctions and Spectrum Access  
Division, WTB.

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## 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 December 12, 2013.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President), 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *CapGen Capital Group III LLC and CapGen Capital Group III LP*, both in New York, New York; to acquire additional voting shares, for a total of 25 percent of, the voting shares of Seacoast Banking Corporation of Florida, and thereby indirectly acquire additional voting shares of Seacoast National Bank, both in Stuart, Florida.

Board of Governors of the Federal Reserve System, November 12, 2013.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2013-27373 Filed 11-14-13; 8:45 am]

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## FEDERAL TRADE COMMISSION

### Public Workshop: Follow-On Biologics: Impact of Recent Legislative and Regulatory Naming Proposals on Competition

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice of workshop and request for comments.

**SUMMARY:** The Federal Trade Commission (“FTC” or “Commission”) announces it will hold a workshop to explore competition issues involving biologic medicines and follow-on biologics. The workshop will focus on the potential impact of state regulations and naming conventions on such competition, including how regulations may be structured to facilitate competition while still protecting patient health and safety. The experience of developing follow-on competition from small-molecule generic drugs will be considered and, as relevant, compared. Topics will include the circumstances under which potential entrants would be willing to invest in the development of follow-on biologics in order to use the abbreviated regulatory approval pathway created by federal legislation. The workshop will also survey the experience of other countries with regulatory systems that enable follow-on biologic competition. This Notice poses a series of questions about which the FTC seeks public comment. The FTC will take these comments into account in its examination of these topics.

**DATES:** The workshop will be held on December 10, 2013, in the FTC headquarters at 600 Pennsylvania Avenue NW., Washington, DC. The FTC workshop is free and open to the public and will also be webcast. Prior to the workshop, the Commission will publish an agenda and further information on its Web site. Comments in response to this notice must be received on or before March 1, 2014.

**ADDRESSES:** Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write “Workshop on Follow-On Biologics: Project No. P131208” on your comment, and file your comment online at <https://ftcpubcommentworks.com/>

*ftc/biologicsworkshop*, by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex X), 600 Pennsylvania Avenue NW., Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Jex, Attorney Advisor, Office of Policy Planning, Federal Trade Commission, 600 Pennsylvania Avenue NW., Washington, DC 20580; (202) 326-3273; [biosimilars@ftc.gov](mailto:biosimilars@ftc.gov).

**SUPPLEMENTARY INFORMATION:** The Federal Trade Commission vigorously promotes competition in the health care industry through enforcement, study, and advocacy. Competition in health care markets benefits consumers by helping to control costs and prices, improve quality of care, promote innovative products, services, and delivery models, and expand access to health care goods and services. As addressed below, this proposed workshop is consistent with these FTC priorities.

### I. Background: Follow-On Competition in Pharmaceutical Markets

In particular, the Commission has sought to protect competition among pharmaceutical products, including generic drugs providing price competition against brand-name drugs. Until relatively recently, the potential for follow-on competition was limited to products involving traditional “small-molecule” generic drugs. Producers of these drugs obtain approval from the Food & Drug Administration (“FDA”) pursuant to an abbreviated regulatory pathway established by the Hatch-Waxman Act.<sup>1</sup>

Biologic medicines have now become among the most important pharmaceutical products in the United States. Biologics comprise the fastest growing sector within pharmaceuticals, and target such difficult to treat diseases as cancer, diabetes, and multiple sclerosis.<sup>2</sup> “Biologics” include, for

<sup>1</sup> See The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* (2011), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 & 35 U.S.C.) (known as Hatch-Waxman), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, § 1112, 117 Stat. 2066, 2461-63 (codified at 21 U.S.C. 355).

<sup>2</sup> *Health Policy Brief: Biosimilars*, Health Affairs 1 (Oct. 10, 2013), [http://healthaffairs.org/healthpolicybriefs/brief\\_pdfs/healthpolicybrief\\_100.pdf](http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_100.pdf) (“[Biologics] account for a substantial and increasing share of the pharmaceutical market and a growing share of health care costs”).