308, 309(j), 310 and 610 of the Communications Act of 1934, as amended.

Total Annual Burden: 13,049 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact.

Nature and Extent of Confidentiality: Information requested in the reports may include confidential information. However, covered entities can request that such materials submitted to the Commission be withheld from public inspection.

Needs and Uses: After the 60-day comment period expires, the Commission will submit the revised information collection to the Office of Management and Budget (OMB) to obtain a full three-year clearance. The changes being made to the information collect concern the Commission's wireless hearing aid combability rules as they relate to the obligations of wireless service providers to post certain information on their websites, retain information and to file annual compliance certifications. No changes are being made to the website posting and reporting burdens of wireless handset manufacturers. Further, no changes are being made to the information collection as related to standards development, labeling and disclosure requirements, and the approved number of estimated respondents/responses.

The revisions to the information collection are necessitated by a Report and Order in WT Docket No. 17–228, FCC 18–167, adopted on November 15, 2018. In this Report and Order, the Commission revised its rules requiring service providers to post on their publicly accessible websites information regarding the hearing aid compatibility of their offered handsets and required them to retain certain information regarding the hearing aid compatibility of handsets they previously offered. Through this information, consumers will have access to the most recent data about hearing aid-compatible handsets and the Commission will be able to ensure compliance with the hearing aid compatibility rules and requirements. In addition, the Commission determined that service providers are no longer required to file FCC Form 655 on an annual basis. Instead, providers must file an annual certification indicating whether they are compliant with the hearing aid compatibility rules.

As part of these revisions to the wireless hearing aid compatibility information collection, the Commission is requesting approval of certain changes to the form and the related instructions. These changes to the form and its instructions implement the new certification compliance requirement for service providers and maintain the existing compliance requirements for device manufacturers. These changes to the form reduce service providers' regulatory burden while continuing to allow the Commission to monitor compliance with the hearing aid compatibility rules.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–03234 Filed 2–25–19; 8:45 am]

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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 March 25, 2019.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org:*

1. *Orrstown Financial Services, Shippensburg, Pennsylvania;* to merge with Hamilton Bancorp, Townson, MD, and thereby indirectly acquire Hamilton Bank, Townson, Maryland.

B. *Federal Reserve Bank of Atlanta* (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *LexPark Holdings—STC, LLC, SouthernTrust Group, LP & SouthernTrust Holdings, Inc., Orlando, Florida;* to become a bank holding company by acquiring voting shares of First City Bank of Florida, Fort Walton Beach, Florida.

Board of Governors of the Federal Reserve System, February 21, 2019.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2019–03297 Filed 2–25–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4367]

Bioavailability Studies Submitted in New Drug Applications or Investigational New Drug Applications—General Considerations; Draft 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 draft guidance for industry entitled ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' This draft guidance provides recommendations to sponsors planning to include bioavailability (BA) information for drug products in investigational new drug applications (INDs), new drug applications (NDAs), and NDA supplements. This draft guidance revises and replaces FDA's March 2014 draft guidance for industry entitled ''Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs—General Considerations,'' which addresses BA or bioequivalence (BE) studies for INDs, NDAs, and NDA supplements.

DATES: Submit either electronic or written comments on the draft guidance by May 28, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.