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]

BILLING CODE 6712–01–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 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]

BILLING CODE P

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.

ADDRESSES: You may submit comments on any guidance 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 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 No. FDA–2018–D–4367 for ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' Received comments 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 or 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dakshina Chilukuri, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1515.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' Determining the BA of formulations is critical during the life cycle of drug products and aids in FDA's evaluation of the safety and effectiveness of a product in an IND, NDA, or NDA supplements. This draft guidance provides recommendations to sponsors planning to include BA information for drug products in INDs, NDAs, and NDA supplements. This draft guidance contains recommendations on how to meet the BA requirements set forth in 21 CFR part 320 as they apply to dosage forms intended for oral administration. The draft guidance is also applicable to non-orally administered drug products when it is appropriate to rely on systemic exposure measures to determine the BA of a drug (*e.g.,* transdermal delivery systems and certain rectal and nasal drug products). The draft guidance provides recommendations on conducting relative BA studies during the IND period for an NDA and BE studies during the postapproval period for certain changes to drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Bioavailability Studies in NDAs or INDs—General Considerations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information submitted under 21 CFR part 312 (INDs) has been approved under OMB control number 0910–0014; and the collection of information submitted under 21 CFR part 314 (NDAs) has been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 20, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03246 Filed 2–25–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3017]

Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is reopening the comment period for the notice entitled ''Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments'' that appeared in the **Federal Register** of November 20, 2018. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice published on November 20, 2018 (83 FR 58574). Submit either electronic or written comments by April 29, 2019.

ADDRESSES: You may submit comments 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 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 No. FDA–2018–N–3017 for ''Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments.'' Received comments 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 or 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.

Submit written requests for single copies of the notice to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave. Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 3330, Silver Spring, MD 20993, 301–796–0151, *chris.wheeler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 20, 2018 (83 FR 58574), FDA published a notice with a 60-day comment period to request comments on the notice entitled ''Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments.'' FDA is reopening the comment period until April 29, 2019. The Agency believes that an additional 60 days will allow adequate time for interested persons to submit comments.

II. Electronic Access

Persons with access to the internet may obtain the notice at either *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 20, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03241 Filed 2–25–19; 8:45 am]

BILLING CODE 4164–01–P