when appropriate, and other forms of information technology.

Background: Many older adults have unmet health care and social service needs, which require coordinated care across a range of services, including access to nutritious meals, transportation, preventive health care, home and community-based care, social interaction, support for family caregivers, and advocacy to help maintain older adults' safety, dignity, and legal rights. This proposed data collection for the Process Evaluation of the Aging Network and its Return on Investment is intended to provide timely information on, (1) how agencies in the Aging Network collaborate to serve older adults and family caregivers, and (2) how agencies measure the effectiveness of their efforts with the goal of strengthening their reach and impact. Through this data collection ACL will investigate how states differ in their network structure, how agencies work together, and potential strategies for evaluating return on investments (ROI) of ACL programs.

The Process Evaluation of the Aging Network and its Return on Investment will include: (1) A census of agencies in the Aging Network, and (2) key informant interviews with agencies that are evaluating ROI. The survey seeks to collect data from all State Units on Aging (SUAs), Area Agencies on Aging (AAAs) (including some Aging and Disability Resource Centers), and Older Americans Act Title VI Native American tribal organizations. Surveying these organizations will help ACL understand how and with whom agencies in the network collaborate to address the needs of older adults and family caregivers, partnerships that have formed or expanded because of COVID–19, and how agencies measure the effectiveness and ROI of their various programs.

The study will also include key informant interviews with a subset of 10 agencies that responded to the survey whose responses indicate that their agency is evaluating ROI. The data collection team will ask in-depth questions about the costs and benefits included in ROI calculations, successes and challenges to evaluating ROI, and lessons learned that could benefit other agencies seeking to conduct their own assessment of ROI.

To comment on this information collection please visit the ACL website: *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows: The proposed data collection estimates the average burden per response to be 0.17 hours for the Aging Network survey. The average burden per response for the key informant interviews estimated as 1 hour.

TABLE 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection activity	Annual number of respondents	Number of responses per respondent	Total number of responses	Average burden per response (in hours)	Annual estimated burden hours
Aging Network survey	864	1	864	0.17	144
Key informant interview guide	10	1	10	1	10
Total	874	Varies	874	0.18 (weighted mean)	154

Dated: August 24, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2021–18588 Filed 8–27–21; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0790]

Breckenridge Pharmaceutical, Inc.; Withdrawal of Approval of Abbreviated New Drug Application for Solifenacin Succinate Tablets, 5 Milligrams and 10 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the abbreviated new drug application (ANDA) for solifenacin succinate tablets, 5 milligrams (mg) and 10 mg, held by Breckenridge Pharmaceutical, Inc., 15 Massirio Dr., Berlin, CT 06037 (Breckenridge). Breckenridge requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of August 30, 2021.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 20, 2019, FDA approved ANDA 209818 for solifenacin succinate tablets, 5 mg and 10 mg, for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. On January 23, 2020, Breckenridge issued a field alert report that solifenacin succinate tablets, 5 mg and 10 mg, may convert to solifenacin tartrate tablets during manufacturing due to an interaction between solifenacin succinate and tartartic acid, which is an inactive ingredient in this drug product's formulation. On January 24, 2020, Breckenridge executed a Class II Recall (Retail-Level) of all solifenacin succinate tablet product lots that were distributed to market. Breckenridge cannot market its solifenacin succinate tablet product under the current approval conditions for ANDA 209818. To the extent that its active ingredient has converted from solifenacin succinate to solifenacin tartrate, the product Breckenridge has distributed under ANDA 209818 is misbranded.

After discussions with FDA, on April 21, 2020, Breckenridge requested that FDA withdraw approval of ANDA 209818 for solifenacin succinate tablets under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. For the reasons discussed above, and in accordance with the applicant's request, approval of ANDA 209818 solifenacin succinate tablets, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of solifenacin succinate tablets into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a)

and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: August 17, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–18586 Filed 8–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–D–0603 and FDA–2021–D–0604]

Safety and Performance Based Pathway Device-Specific Guidances; Draft Guidances for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of two draft device-specific guidance documents for the Safety and Performance Based Pathway—specifically, ''Denture Base Resins—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff'' and ''Facet Screw Systems—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff.'' The device-specific guidances identified in this notice were developed in accordance with the finalized guidance entitled ''Safety and Performance Based Pathway.'' These draft guidance documents are not final nor are they in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by October 29, 2021 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–2021–D–0603 for ''Denture Base Resins—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff'' and Docket No. FDA–2021–D–0604 for ''Facet Screw Systems—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the dockets 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Denture Base Resins—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff'' or ''Facet Screw Systems—Performance Criteria for Safety and Performance Based Pathway; Draft Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jason Ryans, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire