

(2) the accuracy of ACL’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

ACL contracts with a national legal assistance resource center, the National Center on Law and Elder Rights, to provide the required services. Through the contract, ACL provides aging, disability, and related legal professionals with training and complex case consultations and support for demonstration projects regarding contractually identified priority legal

topics. The purpose of the information requested is for ACL to ensure that the resource center creates and prioritizes the training, case consultations and technical assistance resources it was contracted to provide and to ensure that the center targets the contractually designated aging network practitioners about the priority subject matters. This approach enables ACL to make data-informed decisions about the deployment of its resource center assets. These data are necessary for ACL to evaluate contractual compliance with established performance indicators.

These metrics include quantifiable increases in uptake by stakeholders of training, case consultation and technical assistance, and measures of satisfaction with and perceived benefit from these services. For example, the metrics measure successful problem resolution as a result of the services provided and quantifiable data on fulfillment of

requests for training, technical assistance, and consultation related to the contractually designated legal and systems development topic areas. The information requested by ACL from legal and aging/disability professionals falls into the following areas: (1) Requests for training, case consultation, and technical assistance through an online, secure Uniform Resource Support Request Tool; (2) general requests for Legal Training (including the volume of Webinar registrations), Case Consultation.

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:

Respondent/data collection activity	Number of respondents	Minutes per response	Annual burden hours
Resource Support Requests	80	1 min 54 sec	2.53
Legal Training, Case Consultation, Technical Assistance Requests	14,000	1 min 42 sec	397
Outcome Measurement	3,500	1 min 3 sec	61.25
Total	17,580	4 min 39 sec	460.78

Dated: August 23, 2021.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Process Evaluation of the Aging Network and Its Return on Investment; OMB #0985-New

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for

public comment in response to the notice. This notice solicits comments on a revision to the information collection requirements related to the Process Evaluation of the Aging Network and its Return on Investment.

DATES: Comments on the collection of information submitted electronically by 11:59 p.m. (EST) or postmarked by October 29, 2021.

ADDRESSES: Submit written comments on the collection of information:

Attention: Caryn Bruyere, Caryn.Bruyere@acl.hhs.gov.

Via U.S. Mail Attention: Caryn Bruyere U.S. Department of Health and Human Services, Administration for Community Living, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Caryn Bruyere, Office of Performance and Evaluation. Administration for Community Living Telephone: 202-795-7393.

Email: caryn.bruyere@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined as agency requests or requirements that members of the public submit reports,

keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL’s functions, including whether the information will have practical utility;

(2) the accuracy of ACL’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques

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.
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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 tartaric 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)