Dated: September 28, 2017.

William N. Parham, III

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Public Comment Request; Proposed Extension With Changes of a Currently Approved Collection; Evidence-Based Falls Prevention Program

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 certain information by the agency. 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 the information collection requirements relating to ACL's Evidence-Based Falls Prevention Program. This notice solicits comments on a proposed extension with minor changes of a currently approved collection.

DATES: Submit written or electronic comments on the collection of information by December 4, 2017.

ADDRESSES: Submit electronic comments on the collection of information to *shannon.skowronski@acl.hhs.gov.* Submit written comments on the collection of information to: Shannon Skowronski, U.S. Department of Health and Human Services: Administration for Community Living, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Shannon Skowronski at *shannon.skowronski@acl.hhs.gov* or 202–795–7438.

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 in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or update of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on: (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; (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.

The Evidence-Based Falls Prevention Programs is a cooperative agreement financed through the Prevention and Public Health Fund (PPHF), most recently with FY 2017 PPHF funds. The statutory authority for cooperative agreements under the current program announcement is contained in the Public Health Service Act, 42 U.S.C. 300u–2 (Community Programs) and 300u–3 (Information Programs); and Consolidated and Further Continuing Appropriations Act, 2015, Pub. L. 113–235, Div. G., Title II, § 219(a); and the Patient Protection and Affordable Care Act, 42 U.S.C. 300u–11 (Prevention and Public Health Fund).

The Evidence-Based Falls Prevention Programs support a national resource center and award competitive grants to implement evidence-based community programs that have been proven to reduce the incidence of falls for older adults and adults with disabilities (including Tribal elders). The programs also identify sustainable funding mechanisms for these programs via the resource center, promote the importance of falls prevention strategies, and provide public education about the risks of falls and ways to prevent them.

OMB approval of the existing set of Falls Prevention data collection tools (OMB Control Number, 0985–0039) expires on 01/31/2018. This data collection continues to be necessary for monitoring program operations and outcomes. ACL/AoA proposes to use the following tools: (1) Semi-annual performance reports to monitor grantee progress; (2) a Host Organization Data form to record location of agencies that sponsor programs that will allow mapping of the delivery infrastructure; and (3) a set of tools used to collect information at each program completed by the program leaders (Program Information Cover Sheet and Attendance Log), a Participant Information Form completed by each participant, and a Post Program Survey to be completed by a random sample of participants. ACL/AoA intends to continue using an online data entry system for the program and participant survey data. In addition to non-substantive formatting edits, minor changes are being proposed to 2 of the 5 currently approved tools, as indicated below. All changes proposed are based on feedback from a focus group that included a sub-set of current grantees and consultation with subject-matter experts.

- On the Participant Information Form:

1. Additional chronic conditions have been added to the list of options

2. Question #11 (assessing the frequency and impact of falls) has been enhanced to include the location of the fall(s) and further assess impact

3. Two questions have been added (#15 and #16) to examine modifications made to home and activity level

- On the Post-Program Survey:

1. Question #2 (assessing the frequency and impact of falls) has been enhanced to include the location of the fall(s) and further assess impact

2. Questions #6 and #7 have been modified slightly—removing references to home modifications and activity level. Home modifications and activity level are now addressed in questions #8 and #9 instead.

Estimated Annualized Burden Hours

The proposed Falls Prevention Data Collection Tools can be found at ACL's Web site at: *https://www.acl.gov/about-acl/public-input.*

The total estimated burden is 4,345 hours per year. ACL/AoA estimates the burden of this collection of information as 288 hours for project staff, 1,435 hours for local agency staff, and 2,622 hours for individuals.

Type of respondent	Form name	Estimated number of respondents	Number of responses per respondent	Average time per response (in hours)	Total burden hours (annual)
Project staff	Semi-annual Performance Report	18	Twice a year	8	288
Local agency leaders	Program Information Cover Sheet/Participant Information Form/Attendance Log/Post Program Survey.	700 leaders	Twice a year (one set per program).	.50	700
Local data entry staff		46 data entry staff	Once per program x 1400 programs.	.50	700
Local organization staff and local database entry staff.	Host Organization Data Form	700 staff	1	.05	35
Program participants	Participant Information Form	16,390	1	.10	1,639
Program participants	Post Program Survey	983	1	.10	983
Total Burden Hours					4,345

Dated: September 20, 2017.

Mary Lazare,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5437]

Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access.'' The purpose of the public workshop is to provide an overview of current regulatory science initiatives related to generic topical dermatological drug products, solicit public input on scientific barriers that may limit patient access to such drug products, and discuss approaches to overcome/address any such barriers. FDA is seeking public input from a variety of stakeholders, including industry, academia, patient advocates, and professional associations.

DATES: The public workshop will be held on October 20, 2017, from 8:30 a.m. to 4:30 p.m., Eastern Standard Time. Submit either electronic or written comments on this public workshop by November 20, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 20, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 20, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2017–N–5437 for ''Topical Dermatological Generic Drug Products: Overcoming Barriers to Development and Improving Patient Access.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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