

Statutory Authority: 45 CFR 96.81 and 42 U.S.C. 8626(b)(1).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; Chronic Disease Self-Management Education Program Standardized Data Collection

AGENCY: Administration on Aging (AoA), Administration for Community Living (ACL), HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL), Administration on Aging (AoA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written or electronic comments on the collection of information by July 1, 2016.

ADDRESSES: Submit electronic comments on the collection of information to: Submit written comments on the collection of information to by fax 202.395.5806 or by email to OIRA_submission@omb.eop.gov, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Kristie Kulinski (kristie.kulinski@acl.hhs.gov).

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, the Administration for Community Living has submitted the following proposed collection of information to OMB for review and clearance.

The “Empowering Older Adults and Adults with Disabilities through Chronic Disease Self-Management Education (CDSME) Programs” cooperative agreement program has been financed through Prevention and Public Health Funds (PPHF), most recently by FY2015 PPHF funds. The proposed data collection is necessary for monitoring grant program operations and outcomes. AoA proposes to gather information to monitor grantee progress, record location of sites where workshops are held which will allow

mapping of the delivery infrastructure, and document participant attendance and demographic and health characteristics.

The proposed data collection tools may be found on the AoA Web site at: http://www.aoa.acl.gov/AoA_Programs/Tools_Resources/collection_tools.aspx. ACL estimates the burden of this collection of information as 128 hours for grantee staff, 220 hours for local agency staff and volunteers, and 92 hours for individuals—total burden is 440 hours per year. This assumes a data collection sample of 386 workshops.

Dated: May 25, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1254]

Assessing Adhesion With Transdermal Delivery Systems and Topical Patches for Abbreviated New Drug Applications; 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 “Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs.” This draft guidance is intended to provide recommendations for the design and conduct of studies evaluating the adhesive performance of a Transdermal Delivery System or a topical patch (collectively, TDS). This guidance, once finalized, is intended to provide updated recommendations for the design and conduct of adhesion studies submitted in support of an Abbreviated New Drug Application (ANDA) for a TDS.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 1, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2016-D-1254 for “Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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