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

Mary M.Wayland,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2016–12806 Filed 5–31–16; 8:45 am]

BILLING CODE 4184–80–P

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.

[FR Doc. 2016–12866 Filed 5–31–16; 8:45 am]

BILLING CODE 4154–01–P

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

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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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: Kris Andre, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4726, Silver Spring, MD 20993–0002, 240–402–7959.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 provides recommendations for the design and conduct of clinical studies evaluating the adhesive performance of a TDS submitted in support of an ANDA. The recommendations in this guidance relate exclusively to TDS adhesion studies submitted in support of an ANDA.

The amount of drug delivered into and through the skin from a TDS is dependent, in part, on the surface area dosed. It is expected that the entire surface area of a TDS should remain consistently and uniformly adhered to the skin throughout the duration of wear under the conditions of use included in the product label. Under circumstances in which a TDS loses its adherence during wear, the amount of drug delivered to the patient may be reduced.

During the course of the product's labeled wear period, a TDS is reasonably expected to encounter torsional strains arising from anatomical movements, changes in environmental temperature or humidity such as the daily exposure to water (*e.g.,* during routine showering), and contact with clothing, bedding or other surfaces. TDS products that do not maintain consistent and uniform adhesion with the skin under the range of conditions experienced during the labeled wear period for the TDS can result in varying degrees of TDS detachment, including complete detachment, at different times during the course of product wear.

When the adhesion characteristics of a TDS are not sufficiently robust, as evaluated against its labeled conditions of use, the TDS may exhibit variability in the area that is in contact with the skin. In such situations where a TDS is partially detached, there may be uncertainty about the resulting drug delivery profile and, hence, uncertainty about the rate and extent of drug absorption from the TDS. In addition, as the potential for complete detachment of the TDS increases, so does the risk of unintentional exposure of the drug product to an unintended recipient (*e.g.,* a household member who may potentially be a child).

This guidance describes the recommended approach to the adhesion clinical study design and, therefore, will supersede the recommendations related to adhesion studies provided in individual product-specific guidances published prior to the date of publication of this guidance. This guidance, once finalized, is intended to provide updated recommendations for the design and conduct of adhesion studies submitted in support of an ANDA for a TDS. FDA recommends that applicants consult this guidance in conjunction with any relevant product-specific guidance documents when considering other studies (*e.g.* irritation, sensitization) that may be necessary to support the bioequivalence (BE) of a proposed generic TDS drug product to its RLD.

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 ''Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs.'' 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.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: May 26, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–12822 Filed 5–31–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–1235]

Determination of Regulatory Review Period for Purposes of Patent Extension; OSPHENA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for OSPHENA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 1, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence