information to: *kristie.kulinski@acl.hhs.gov.* Submit written comments on the collection of information to Kristie Kulinski, U.S. Administration for Community Living, Administration on Aging, 330 C Street SW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Kristie Kulinski (*kristie.kulinski@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 in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request 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 of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, AoA 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 ''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 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).

OMB approval of the existing set of CDSME data collection tools (OMB Control Number, 0985–0036) expires on 07/31/2016. This data collection continues to be necessary for monitoring program operations and outcomes. ACL proposes to use revised versions of the following tools: (1) Semi-annual progress reports to monitor grantee progress; (2) an Organization Data form to record location of sites where programs are held which 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/delivery personnel (Program Information Cover Sheet and Attendance Log) and a Participant Information Survey completed by each participant to document their demographic and health characteristics. ACL is not requesting renewal of one other data collection tool, the Annual Integrated Services Delivery System Assessment Tool. ACL proposes to gather data using an existing online data entry system for the program and participant survey data. The current proposed Data Collection Tools can be found at ACL's 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: March 1, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–04924 Filed 3–4–16; 8:45 am]

BILLING CODE 4154 –01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Senior Medicare Patrol (SMP) Program Outcome Measurement

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) 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 comments on the collection of information by May 6, 2016.

ADDRESSES: Submit written comments on the collection of information by fax 202–395–5806 or by email to *OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Phillip McKoy at 202–795–7397 or email: *phillip.mckoy@acl.hhs.gov*.

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

Grantees are required by Congress to provide information for use in program monitoring and for Government Performance and Results Act (GPRA) purposes. This information collection reports the number of active volunteers, issues and inquiries received, other SMP program outreach activities, and the number of Medicare dollars recovered, among other SMP performance outcomes. This information is used as the primary method for monitoring the SMP Projects.

ACL estimates the burden of this collection of information as follows: *Respondents:* 54 SMP grantees at 23 hours per month (276 hours per year, per grantee). *Total Estimated Burden Hours:* 7,452 hours per year.

Dated: March 1, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–04925 Filed 3–4–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0668]

Mechanistic Oral Absorption Modeling and Simulation for Formulation Development and Bioequivalence Evaluation; 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 or the Agency) is

announcing a public workshop entitled ''Mechanistic Oral Absorption Modeling and Simulation for Formulation Development and Bioequivalence Evaluation.'' The purposes of the workshop are to share current FDA experiences on the application of mechanism-based absorption modeling and simulation in regulatory activities; discuss current and future utility of mechanism-based absorption modeling and simulation in the development of bioequivalent oral drug products and regulatory reviews; obtain input from various stakeholders on when, where, and how to conduct mechanism-based absorption modeling and simulations in the context of bioequivalent product development; and request comments on these topics.

DATES: The public workshop will be held on May 19, 2016, from 8:30 a.m. to 4:30 p.m. Individuals who wish to attend the workshop must register by April 19, 2016. The deadline for submitting either electronic or written comments on this workshop is June 20, 2016. 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 *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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. Since 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–N–0668 for ''Mechanistic Oral Absorption Modeling and Simulation for Formulation Development and Bioequivalence Evaluation; Public Workshop; Request for Comments.'' 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.

FOR FURTHER INFORMATION CONTACT: Xinyuan Zhang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4612, Silver Spring, MD 20993, 240–402–7971, email: *Xinyuan.Zhang@fda.hhs.gov;* or Liang Zhao, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4606, Silver Spring, MD 20993, 240–402–4468, email: *Liang.Zhao@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In July 2012, Congress passed the Generic Drug User Fee Amendments (GDUFA) (Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144)). GDUFA is designed to enhance public access to safe, high-quality generic drugs and reduce costs to industry. To support this goal, FDA agreed in the GDUFA commitment letter to work with industry and interested stakeholders on identifying regulatory science research priorities specific to generic drugs for each fiscal year covered by GDUFA. The commitment letter outlines FDA's performance goals and procedures under the GDUFA program for the years 2012 to 2017. The commitment letter can be found at *http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.*

In the Regulatory Science section of the GDUFA Commitment Letter, FDA outlined its plans to advance regulatory science, including with respect to modeling and simulation. To enhance communication of recent advances in modeling and simulation, including those supported by GDUFA funds, FDA plans to hold a public workshop on

mechanistic oral absorption modeling and simulation. Mechanism-based absorption modeling and simulation is a computational tool that integrates drug substance information, drug product information, drug product in vitro performance, and physiological properties of the human body to predict drug product pharmacokinetics in vivo. Modeling simulation studies may also, in principle, be used as a tool to elucidate dissolution boundaries that have high likelihood of remaining bioequivalence, and those boundaries can be used to inform clinically relevant dissolution specifications. Models developed in a mechanistic manner integrating all available knowledge relevant to the absorption process lend great value for development of bioequivalent oral drug products and regulatory evaluation because the main differences between the reference drug products and the bioequivalent products (*e.g.,* the difference in formulation factors) are taken into account in the model.

II. Purpose and Scope of the Workshop

The purpose of the workshop is to:

1. Share FDA's current experiences on the application of mechanism-based absorption modeling and simulation in regulatory activities;
2. Discuss the current and future utility of mechanism-based absorption modeling and simulation in development of bioequivalent oral drug products and regulatory reviews; and
3. Obtain input from the public on when, where, and how mechanism-based absorption modeling and simulation should be applied in development of bioequivalent oral drug products and review of bioequivalence.

The scope of the workshop covers the current status of mechanism-based absorption modeling and simulation from academia, industry, and regulatory perspectives.

The majority of drug products on the market are administered orally. Predicting oral bioavailability is always of great interest for pharmaceutical scientists. It has been a long journey for scientists to develop mechanistic absorption models for oral bioavailability prediction to reduce drug development time and cost, and to inform regulatory decisions. From simpler models to more complex ones, mechanism-based absorption models have been advanced substantially and their applications have been increasingly found in scientific literature and regulatory reports.

The high value of leveraging mechanistic absorption models in the development and evaluation of bioequivalent drug products can be attributed to their incorporation of formulation factors. The focus of this public workshop is on the application of mechanistic absorption modeling and simulation for development of bioequivalent oral drug products and evaluation of bioequivalence, including discussing the areas in which mechanistic oral absorption models can contribute significantly, how the mechanistic absorption modeling and simulation should be conducted and evaluated, and inherent scientific challenges.

Public input will improve FDA's current understanding of using mechanism-based absorption modeling and simulation in bioequivalence evaluation. The knowledge gained from, and consensus reached, through this workshop will be summarized and disseminated to the scientific community by publication(s).

III. Scope of Public Input Requested

FDA seeks input from the public on when, where, and how to utilize mechanism-based absorption modeling and simulation in the context of development of bioequivalent oral drug products and regulatory evaluation of bioequivalence. Specific topics to be addressed include:

1. Identifying the areas in which mechanistic oral absorption models can contribute significantly during development of bioequivalent oral drug products and regulatory evaluation of bioequivalence;
2. How mechanistic absorption modeling and simulation should be conducted and evaluated; and
3. The scientific challenges in mechanistic oral absorption and simulation.

Registration and Requests for Attendee Participation: The FDA Conference Center at the White Oak Campus is a Federal facility with security screening and limited seating. Individuals who wish to attend the public workshop (either in person or by Webcast (see *Streaming Webcast of the Public Workshop*)) must register on or before April 19, 2016, by sending a request to *CDER-OGD-OfficeofResearchandStandardsAnnouncement@fda.hhs.gov* with their complete contact information (*i.e.,* name, title, affiliation, address, email address, and telephone number).

There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Xinyuan Zhang (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

The workshop agenda and other background materials will be available approximately 2 weeks before the workshop at *http://www.fda.gov/Drugs/NewsEvents/ucm488178.htm.* The agenda will include time for questions and answers throughout the day and for general comments and questions from the audience following panel discussions.

In this document, FDA has included specific issues that will be addressed by the panel. If you wish to address one or more of these issues, please submit your comments via the Docket or speak during the public comments session at the workshop. If you wish to speak during the public comments session at the workshop, please indicate it at the time you register so that FDA can consider that in planning the agenda. FDA will do its best to accommodate requests to speak.

Streaming Webcast of the Public Workshop: A live Webcast of this workshop will be viewable at *https://collaboration.fda.gov/r6gjahu3ejv* on the day of the workshop. The live Webcast will be in a listening only mode.

Transcripts: Transcripts of the workshop will be available for review at *http://www.fda.gov/Drugs/NewsEvents/ucm488178.htm* at the Division of Dockets Management (see **ADDRESSES**), and at *http://www.regulations.gov* approximately 30 days after the workshop. A transcript will also be available, in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.*

Dated: March 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04965 Filed 3–4–16; 8:45 am]

BILLING CODE 4164–01–P