

published September 14, 2016 (81 FR 63187). Submit either electronic or written comments by March 13, 2017.
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-2635 for "Establishing Appropriate Durations of Therapeutic Administration." 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: Cindy Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0817, cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 14, 2016 (81 FR 63187), FDA solicited comments regarding the establishment of appropriate durations of use of antimicrobial drugs of importance to human medicine when administered in the feed or water of food-producing animals for therapeutic purposes with a 90-day comment period.

The Agency has received requests for an extension of the comment period. These requests conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the request for comments.

FDA has considered the requests and is extending the comment period for 90 additional days, until March 13, 2017. The Agency believes that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying FDA's consideration of these important issues.

Dated: November 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-28660 Filed 11-28-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0067]

Pharmaceutical Science and Clinical Pharmacology Advisory Committee; Establishment of a Public Docket; Request for Comments; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on March 15, 2017, from 7:30 a.m. to 3:45 p.m.

ADDRESSES: Omni Shoreham Hotel, the Ballroom, 2500 Calvert St. NW., Washington, DC 20008. The hotel telephone number is 202-234-0700. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

You may submit comments as follows:

Electronic Submissions

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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-2010-N-0067 for "Pharmaceutical Science and Clinical Pharmacology Advisory Committee; Notice of Meeting." 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:

Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, ACPS-CP@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The use of model-informed drug development (MIDD) for new and generic drugs has significantly increased over the past several years. The committee will discuss strategies, approaches, and challenges in MIDD with specific focus on two areas. During the morning session, the committee will discuss approaches and evidentiary

information needed for applying physiologically-based pharmacokinetic modeling and simulation throughout a drug's lifecycle. During the afternoon session, the committee will discuss mechanistic model-informed safety evaluation with a focus on drug potential for causing arrhythmias. The Comprehensive in Vitro Proarrhythmia Assay will be discussed as an exemplar.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before March 1, 2017, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 9:50 a.m. to 10:20 a.m. and 2:15 p.m. to 2:45 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 21, 2017. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 22, 2017.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jennifer

Shepherd at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-28605 Filed 11-28-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Chronic Fatigue Syndrome Advisory Committee

AGENCY: Office of the Assistant Secretary for Health, Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that a meeting of the Chronic Fatigue Syndrome Advisory Committee (CFSAC) will take place. This meeting will be open to the public.

DATES: Thursday, January 12, 2017, from 12:00 p.m. to 5:00 p.m. ET, and Friday, January 13, 2017, from 9:00 a.m. to 5:00 p.m. ET.

ADDRESSES: Individuals may attend this meeting in person and/or by utilizing virtual technology. Information for in-person attendance will be posted on the CFSAC Web site, <http://www.hhs.gov/ash/advisory-committees/cfsac/meetings/index.html>. Registration is required for in-person attendance. Information on the procedure to follow for registration will be included on the CFSAC Web site. For individuals wishing to attend the meeting virtually, a webinar will be offered. Information about accessing the webinar will be included on the CFSAC Web site.

FOR FURTHER INFORMATION CONTACT: Gustavo Seinos, MPH, Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Department of Health and Human Services, 200 Independence Avenue SW., Room 712E, Washington, DC 20201. Please direct all inquiries to cfsac@hhs.gov.

SUPPLEMENTARY INFORMATION: The CFSAC is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The purpose of the CFSAC is to provide advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health on topics related to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The issues can include factors affecting access and care for persons with ME/CFS; the science and definition of ME/CFS; and broader public health, clinical, research, and educational issues related to ME/CFS.

The agenda for this meeting, call-in information, and location will be posted on the CFSAC Web site <http://www.hhs.gov/ash/advisory-committees/cfsac/meetings/index.html>.

Thirty minutes will be allotted for public comment via telephone or in person on each day of the meeting. Each individual will have three minutes to present their comments. Priority will be given to individuals who have not provided public comment within the previous year. We are unable to place international calls for public comments. Individuals are required to register to participate in the public comment sessions. To request a time slot for public comment, please send an email to cfsac@hhs.gov by January 5, 2017. The email should contain the speaker's name and the telephone number at which the speaker can be reached for the public comment session.

Individuals who would like for their testimony to be provided to the Committee members should submit a copy of the testimony prior to the meeting. It is preferred, but not required, that the submitted testimony be prepared in digital format and typed using a 12-pitch font. Copies of the written comment must not exceed 5 single-space pages, and it is preferred, but not required that the document be prepared in the MS Word format. Please note that PDF files, charts, and photographs cannot be accepted. Materials submitted should not include sensitive personal information, such as Social Security number, birthdate, driver's license number, passport number, financial account number, or credit or debit card number. If you wish to remain anonymous, then document must specify this.

The Committee welcomes input on any topic related to ME/CFS.

Gustavo Seinos,

Designated Federal Officer, CDR, USPHS.

[FR Doc. 2016-28723 Filed 11-28-16; 8:45 am]

BILLING CODE 4150-42-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing and Collaboration

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention: Genetically Engineered Mouse-Derived Allograft for Use in Preclinical Studies of Metastatic Melanoma Therapies.

Keywords: Melanoma, GDA, Allograft, Genetically Engineered Mouse, immunological response.

Description of Technology: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development.

Before testing drugs in humans, drug developers are required to demonstrate a reasonable expectation of safety and efficacy by performing so-called pre-clinical studies. A key element of such trials is the use of animal models,