of value to physicians and teaching hospitals, as well as, certain information regarding the ownership or investment interests held by physicians or their immediate family members in applicable manufacturers or applicable GPOs.

Specifically, applicable manufacturers of covered drugs, devices, biologicals, and medical supplies are required to submit on an annual basis the information required in section 1128G(a)(1) of the Act about certain payments or other transfers of value made to physicians and teaching hospitals (collectively called covered recipients) during the course of the preceding calendar year. Similarly, section 1128G(a)(2) of the Act requires applicable manufacturers and applicable GPOs to disclose any ownership or investment interests in such entities held by physicians or their immediate family members, as well as information on any payments or other transfers of value provided to such physician owners or investors. Applicable manufacturers must report the required payment and other transfer of value information annually to CMS in an electronic format. The statute also provides that applicable manufacturers and applicable GPOs must report annually to CMS the required information about physician ownership and investment interests, including information on any payments or other transfers of value provided to physician owners or investors, in an electronic format by the same date. Applicable manufacturers and applicable GPOs are subject to civil monetary penalties (CMPs) for failing to comply with the reporting requirements of the statute. We are required by statute to publish the reported data on a public Web site. The data must be downloadable, easily searchable, and aggregated. In addition, we must submit annual reports to the Congress and each state summarizing the data reported. Finally, section 1128G of the Act generally preempts state laws that require disclosure of the same type of information by manufacturers. *Form Number:* CMS–10495 (OMB Control Number: 0938–1237); *Frequency:* Once; *Affected Public:* Private sector—Business or other for-profits; *Number of Respondents:* 227,157; *Total Annual Responses:* 457,454; *Total Annual Hours:* 3,099,297. (For policy questions regarding this collection contact Veronika Peleshchuk Fradlin at 410–786–3323.)

Dated: February 22, 2017.

William N. Parham, III,

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

[FR Doc. 2017–03809 Filed 2–24–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0696]

Current State and Further Development of Animal Models of Serious Infections Caused by Acinetobacter baumannii and Pseudomonas aeruginosa; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding the current state and further development of animal models for serious infections caused by *Acinetobacter baumannii* and *Pseudomonas aeruginosa.* FDA is conducting this workshop in order to facilitate the development of narrow-spectrum antibacterial drugs, such as those that are active against only a single species of bacteria that may not occur frequently.

This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. Government Agencies, academic experts, contract research organizations, and industry on various aspects of development efforts pertaining to animal models of serious infections. The input from this public workshop will also help FDA in developing topics for future discussion.

DATES: The public workshop will be held on March 1, 2017, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public workshop by March 15, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration information. The workshop draft Agenda will be made available at: *http://www.fda.gov/Drugs/NewsEvents/ucm534031.htm* prior to the meeting.

ADDRESSES: The public workshop will be held at the DoubleTree by Hilton Hotel Washington DC-Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910. The hotel's phone number is 301–589–5200.

You may submit comments as follows:

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):* 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–2017–N–0696 for ''Current State and Further Development of Animal Models of Serious Infections Caused by *Acinetobacter baumannii* and *Pseudomonas aeruginosa.*'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://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 *https://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 the electronic and written/paper comments received, go to *https://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: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding animal model development for infectious diseases. FDA is conducting this workshop in order to facilitate the development of narrow-spectrum antibacterial drugs, such as those that are active against only a single species of bacteria that may not occur frequently. When the species occurs infrequently, performing clinical trials can be extremely challenging. Therefore, animal models of infection may be useful to explore the activity of a candidate antibacterial drug and may help to predict whether the drug will be efficacious in humans. A discussion of the additional scientific work needed to evaluate current animal models of infection and evaluate potential animal models that may predict response in humans could advance the development of antibacterial drugs targeting a single species.

FDA is particularly interested in infections due to *Acinetobacter baumannii* and *Pseudomonas aeruginosa* as pathogens because there are limited therapeutic options to treat patients with serious infections caused by these bacteria, including those resistant to currently available antibacterial drugs. In addition, it is difficult to enroll an adequate number of patients to conduct clinical trials since the frequency with which these organisms cause clinical disease is sufficiently low. Discussions will focus on the current state of animal models of serious infections, lessons learned from the development efforts for past and current animal models of infection, and scientific challenges and future direction and next steps in animal model development.

This public workshop is intended to provide information for and gain perspective from health care providers, other U.S. Government Agencies, academic experts, contract research organizations, and industry on various aspects of development efforts pertaining to animal models of serious infections. The input from this public workshop will also help FDA in developing topics for future discussion. The Agency encourages health care providers, other U.S. Government Agencies, academic experts, contract research organizations, industry, and other interested persons to attend this public workshop.

Registration: Interested parties are encouraged to register early. To register electronically, email registration information (including name, title, firm name, address, telephone, and fax number) to *AnimalModelsInfectionWorkshop2017@fda.hhs.gov.* Persons without access to the Internet can call 301–796–1300 to register. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. All requests to make oral presentations must be received by February 27, 2017. We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants on or before February 28, 2017. If selected for presentation, any presentation materials must be emailed to *AnimalModelsInfectionWorkshop2017@fda.hhs.gov* no later than February 28, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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.* Transcripts will also be available on the Internet at: *http://www.fda.gov/Drugs/NewsEvents/ucm534031.htm* approximately 45 days after the workshop.

Dated: February 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–03751 Filed 2–24–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which