additional countries may be assessed for risk of 2019–nCoV infection at U.S. airports.

The information collected will be limited to that necessary to confirm the individual's identity, establish their travel itinerary, and make a public health risk assessment. This includes travel itinerary data, information about who the traveler is, and contact and locating information sufficient to complete potential follow-up after arrival. CDC will also observe travelers to determine if the traveler is experiencing any overt signs and symptoms of disease, as well as ask basic questions about signs or symptoms of illness. The information also includes a field for a temperature, which will be taken via a non-contact thermometer. CDC will require all travelers from Wuhan, China, and any symptomatic travelers from China, to provide information as part of an initial public health risk assessment. Travelers from other areas may be required to answer questions as part of a risk assessment if there is a demonstrated risk of exportation to the United States.

If an individual from an area where the virus is spreading has a fever, answers ''Yes'' to any of the symptom questions, or has visible signs of specific symptoms, they will be required to undergo a further public health evaluation that will ask more in-depth health and exposure-related questions.

In the event that there is a repatriation of U.S. citizens or other groups from foreign countries to the United States, and those individuals are coming from areas experiencing an outbreak of 2019-nCoV, individuals may be required to respond to a pre-boarding health screening and a questionnaire to assess their risk of infection depending on the risk of exposure. CDC may monitor individuals repatriated to the United States from areas experiencing an outbreak of 2019-nCoV for symptoms associated with the disease for a period of up to two weeks (14 days) after arrival, depending on exposure risks and whether or not they develop symptoms.

CDC is also seeking authorization to ask state and local health departments to administer questionnaires to air travelers who may have been exposed to a case of 2019-nCoV. In the event a confirmed case of 2019-nCoV flew to the United States, CDC will distribute the questionnaires to state health departments and ask them to make contact with their respective residents to determine if additional public health follow-up is needed. CDC will then ask the state health department to return the completed questionnaires. In limited circumstances, CDC may make direct contact with the at-risk travelers. There are no costs to respondents other than their time. The total estimated burden hours requested are 36,751.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (in minutes)	Total burden hours
Traveler	United States Travel Health Declaration (English or Mandarin Chinese).	100,000	1	10/60	16,667
Traveler	United States Travel Health Declaration for Repatriation.	5,000	1	15/60	1,250
Traveler	2019n-CoV Supplemental Questionnaire	5,000	1	15/60	1,250
Traveler	Preboarding Health Screen	5,000	1	5/60	417
Traveler	2019-nCoV Air CI Basic Questionnaire	5,500	1	30/60	2,750
Traveler	2019-nCoV Air CI Follow-up Questionnaire	5,500	1	30/60	2,750
Traveler	2019-nCoV Daily Symptom Check	5,000	28	5/60	11,667
Total					36,751

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–02266 Filed 2–4–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4337]

Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the following public meeting entitled ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.'' The purpose of the public meeting and the request for comments is to fulfill FDA's commitment to seek stakeholder input related to data standards and the electronic submission system's past performance, future targets, emerging industry needs, and technology initiatives. FDA will use the information from the public meeting as well as from comments submitted to the docket to inform data standards initiatives, FDA Information Technology (IT) Strategic Plan, and electronic submissions gateway target timeframes.

DATES: The public meeting will be held on April 22, 2020, from 9 a.m. to 4 p.m. Submit either electronic or written comments on this public meeting by April 22, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and securing information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 22, 2020. The *https://www.regulations.gov* electronic filing

system will accept comments until 11:59 p.m. Eastern Time at the end of April 22, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–N–4337 for ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 Dockets Management Staff. 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 laws. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or 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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035, *chenoa.conley@fda.hhs.gov,* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is committed to achieving the long-term goal of improving the predictability and consistency of the electronic submission process and enhancing transparency and accountability of FDA information technology-related activities. In the Prescription Drug User Fee Act (PDUFA) VI commitment letter, FDA agreed to hold annual public meetings to seek stakeholder input related to electronic submissions and data standards to inform the FDA IT Strategic Plan and published targets. The commitment letter outlines FDA's performance goals and procedures under the PDUFA program for the years 2018 through 2022. The commitment letter can be found at *https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm.*

FDA will consider all comments made at this meeting or received through the docket (see **ADDRESSES**).

II. Participating in the Public Meeting

Registration: To register to attend ''Prescription Drug User Fee Act of 2017; Electronic Submissions and Data Standards,'' please visit the following website: *https://www.eventbrite.com/e/pdufa-vi-2020-public-meeting-on-electronic-submissions-and-data-standards-tickets-73294889989.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. A draft agenda will be posted approximately 1 month prior to the meeting.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by 11:59 p.m. Eastern Time on April 1, 2020. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

Request for Oral Presentations: During the request for comment period, you may indicate if you wish to present at the public meeting and which topic(s) you would like to address. FDA will do its best to accommodate requests to make an oral presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations. Following the close of registration, FDA 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 by April 8, 2020. All requests to make oral presentations must be received by the close of registration at 11:59 p.m. Eastern Time

on April 1, 2020. If selected for presentation, any presentation materials must be emailed to *cderdatastandards@fda.hhs.gov* no later than April 15, 2020. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast: *https://collaboration.fda.gov/pdufa042220/.*

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

If you need special accommodations due to a disability, please contact Chenoa Conley, (see **FOR FURTHER INFORMATION CONTACT**) no later than April 1, 2020.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm446608.htm.*

Dated: January 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02163 Filed 2–4–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–6046]

Advancing Animal Models for Antibacterial Drug Development; 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, the Agency, or we) is announcing the following public workshop entitled ''Advancing Animal Models for Antibacterial Drug Development.'' The purpose of the public workshop is to discuss progress and challenges in the development of various animal models for serious infection funded by FDA, the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA) to facilitate antibacterial drug development, and to discuss ideas for future research. This public workshop is a follow up to the FDA public workshop held on March 1, 2017, entitled ''Current Status and Future Development of Animal Models of Serious Infections Caused by *Acinetobacter baumannii* and *Pseudomonas aeruginosa.*''

DATES: The public workshop will be held on March 5, 2020, from 8:30 a.m. to 4 p.m. Submit either electronic or written comments on this public workshop by April 6, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. 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 *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 6, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on April 6, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2019–N–6046 for ''Advancing Animal Models for Antibacterial Drug Development.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 Dockets Management Staff. 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