information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The COVID–19 risk questionnaire asks participants whether or not they display COVID–19 symptoms, whether or not they have had close contact with individuals known to test positive for COVID–19, and whether or not they have been tested for COVID–19. The questionnaire also requests temperature checks on individuals. This will help to reduce possible exposure to the virus and help protect the health and safety of both UAC and program staff.

Respondents: Staff and visitors at UAC program sites.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual responses per respondent	Average burden hours per response	Annual burden hours
UAC COVID–19 Risk Questionnaire	15,000	260	.033	128,700

Authority: 6 U.S.C. 279(b)(1)(B);(E).

Emily Ball Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–19024 Filed 8–27–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Patient Engagement Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Patient Engagement Advisory Committee. The general function of the committee is to provide advice to the Commissioner, or designee, on complex issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public.

DATES: The meeting will take place virtually on October 22, 2020, from 10 a.m. Eastern Time to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Information on how to access the webcast will be made available no later than 2 business days prior to the meeting at *www.fdalive.com/PEAC.*

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002, *letise.williams@fda.hhs.gov,* 301–796–8398, 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 website at *https://www.fda.gov/advisory-committees* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On October 22, 2020, the committee will discuss and make recommendations on the topic ''Artificial Intelligence (AI) and Machine Learning (ML) in Medical Devices.'' Specifically, we will discuss the composition of the datasets on which the software ''learns'', components of the device information shared with patients, and factors that impact patient trust in the technology. Large clinical datasets are used to train and improve AI/ML algorithms, allowing transformational improvements in the diagnosis, clinical decision making, and treatment of patients. Devices using AI/ML technology will transform healthcare delivery by increasing efficiency of key processes in the treatment of patients. Health products powered by AI/ML are streaming into our lives, from virtual doctor apps to wearable sensors and drugstore chatbots to algorithms for detecting cancer in mammography and interpretations of chest X rays. Despite the rapid advancement and integration, AI/ML systems may have algorithmic biases, limited generalizability, and lack transparency in their assumptions based on potential limitations of training datasets. The recommendations provided by the committee will address the importance of including various demographic groups in AI/ML algorithm development. The recommendations will also address the impact of the user interface and transparency including what information and how the information about the devices could be communicated to foster patient trust in the AI/ML devices.

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 website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background materials will be available at *https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee.* Select the link for the 2020 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Oral presentations

from the public will be scheduled on October 22, 2020, between approximately 1:30 p.m. Eastern Time to 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include 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 September 22, 2020. 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 September 24, 2020. Individuals who do not wish to speak at the open public hearing session but would like their comments to be heard by the committee may send written submissions to the contact person on or before September 30, 2020.

Virtual Breakout Session:

Individuals interested in participating in the virtual breakout scenario discussion will need to signup to participate on or before October 8, 2020. The signup sheet, as well as, additional information pertaining to the virtual scenario discussion will be available at *https://www.fdalive.com/peac/.* Please note due to limited technology capacity, participation in the virtual breakout scenario discussion will be limited to 150 participants. The first 150 participants to sign up for the virtual breakout scenario discussion will receive a Zoom access link that will provide them with access to their assigned breakout room. Participants will receive the Zoom link no later than 2 days prior to the meeting. Individuals participating in the virtual breakout scenario discussion will only have access to Zoom during the time of the virtual breakout scenario discussion. Participants will need to sign out of the webcast and log into the Zoom at the time of the virtual breakout scenario discussion. Once the virtual breakout scenario discussion concludes participants will be signed out from Zoom and will need to log back into the webcast to participate in the remainder of the meeting.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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 AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov,* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings* for procedures on public conduct during advisory committee meetings. Please be advised that, during the virtual scenario breakout discussions, FDA will prepare a summary of the discussion in lieu of detailed transcripts.

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

Dated: August 21, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–18953 Filed 8–27–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1767]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 9, 2020, from 8 a.m. to 5 p.m., Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1767. The docket will close on October 8, 2020. Submit either electronic or written comments on this public meeting by October 8, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 8, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 8, 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.

Comments received on or before September 25, 2020, will be provided to the committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate. 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