SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On September 22, 2022, the committee will meet in open session to discuss BLA 125739 from Rebiotix Inc., for a product REBYOTA (Fecal Microbiota, Live), with a requested indication to ''reduce the recurrence of *Clostridioides difficile* infection (CDI) in adults following antibiotic treatment for recurrent *Clostridioides difficile* infection.''

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 at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. 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. All electronic and written submissions submitted to the Dockets (see **ADDRESSES**) on or before September 14, 2022, will be provided to the committee. Comments received after September 14, 2022, and by September 21, 2022, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 1:50 p.m. and 2:50 p.m. Eastern Time. 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, along with their names, email addresses, and direct contact phone numbers of proposed participants, on or before 12 p.m. Eastern Time on September 14, 2022. 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 6 p.m. Eastern Time September 16, 2022.

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 Sussan Paydar or Prabhakara Atreya (see **FOR FURTHER INFORMATION CONTACT**) 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/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: August 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17059 Filed 8–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Agency Information Collection Activities; Proposed Collection; Comment Request; Q-Submission Program for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collections associated with the Q-Submission Program for medical devices.

DATES: Either electronic or written comments on the collection of information must be submitted by October 11, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 11, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2012–D–0530 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Q-Submission Program for Medical Devices.'' 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, 240–402–7500.

• 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 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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 requests 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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.

Q-Submissions Program for Medical Devices

OMB Control Number 0910–0756—Revision

The guidance entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' (*https://www.fda.gov/media/114034/download*) provides an overview of the mechanisms available to submitters through which they can request feedback from, or a meeting with, FDA regarding certain potential or planned medical device submissions reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding certain types of Q-Submissions, such as Pre-Submissions, Submission Issue Requests, Study Risk Determinations, Informational Meetings, and other Q-Submission types and other uses of the Q-Submission Program.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 3,700 submissions is based on recent trends. FDA's administrative and technical staffs, who are familiar with Q-Submissions, estimate that an average of 137 hours is needed to prepare a Q-Submission.

Early Payor Feedback Program

Prior to submitting a Pre-Submission, medical device sponsors may request that one or more payor organizations join a Pre-Submission meeting. Payors include public payors such as Centers for Medicare & Medicaid Services, private health plans, health technology assessment groups, and others who provide input into coverage, procurement, and reimbursement decisions. To facilitate such opportunities to obtain payor input, FDA provides information about our Early Payor Feedback Program (EPFP) and a list of current payor participants on our website (*https://www.fda.gov/about-fda/cdrh-innovation/payor-communication-task-force#2*). For payors to decide which devices to provide feedback on, we have developed a voluntary form for manufacturers to provide basic information regarding their device. This form is shared with the payors from whom the manufacturer is requesting feedback. We expect preparation and submission of the form to take no more than 2 hours.

eSTAR for Q-Submissions

Under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), and consistent with the Medical Device User Fee Amendments 2017 (MDUFA IV) Commitment Letter and the FDA guidance document entitled ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act'' (*https://www.fda.gov/media/131064/download*), FDA has developed an ''electronic Submission Template and Resource'' (eSTAR) for Q-submissions to facilitate the preparation of submissions in electronic format (*https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program*). The use of eSTAR for Q-Submissions is currently voluntary. We assume approximately 40 percent of Q-Submissions will use eSTAR and that preparation using eSTAR will take approximately half the time of preparing a submission without using eSTAR.

We estimate a setup burden of 5 minutes for new eSTAR users. Respondents will only need to set up eSTAR the first time they use it. We note that because some respondents

may have already undergone eSTAR set up for other types of submission, *e.g.,* premarket notification, fewer respondents may need to undergo eSTAR setup than estimated.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"					
Q-Submissions:					
CDRH	2,160	1	2,160	137	295,920
CBER	60	1	60	137	8,220
Q-Submissions Using eSTAR (21 CFR Part 814, Subparts A Through E; Section 745A(b) of the FD&C Act)					
CDRH	1,440	1	1,440	69	99,360
CBER	40	1	40	69	2,760
eSTAR setup	1,480	1	1,480	0.08 (5 minutes)	118
Manufacturer request to participate in EPFP	30	1	30	2	60
Total					406,438

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Including the EPFP form represents a revision to this information collection request. Our estimated burden for the information collection reflects the availability of eSTAR to assist electronic preparation of Q-submissions and addition of the EPFP form, resulting in an overall decrease of 85,803 hours.

Dated: August 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17058 Filed 8–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board Public Meeting

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Biodefense Science Board (NBSB or the Board), authorized under Section 319M of the Public Health Service (PHS) Act, as added by Section 402 of the Pandemic and All-Hazards Preparedness Act of 2006 and amended by Section 404 of the Pandemic and All-Hazards Preparedness Reauthorization Act, will hold a public meeting. The NBSB provides expert advice and guidance to the Department of Health and Human Services (HHS) regarding current and future chemical, biological, radiological, and nuclear threats, as well as other matters related to disaster preparedness and response. The Assistant Secretary for Preparedness and Response (ASPR) manages and convenes the NBSB on behalf the Secretary. A detailed agenda and Zoom registration instructions will be posted on the ASPR website at least two weeks in advance.

DATES: The public meeting will be held on September 29, 2022 beginning at 11 a.m. Eastern time.

FOR FURTHER INFORMATION CONTACT: CAPT Christopher Perdue, NBSB Designated Federal Official, *NBSB@hhs.gov,* 202–401–5837.

SUPPLEMENTARY INFORMATION: Those interested may attend the meeting via a toll-free phone number or Zoom teleconference, which requires pre-registration. The meeting link to pre-register will be posted on the meeting website. The online meeting will include American Sign Language interpretation and live captioning.

Members of the public may provide written comments or submit questions at any time via email to *NBSB@hhs.gov*. Additionally, the NBSB invites stakeholders to request up to seven minutes to address the Board in-person during the meeting. The Board wishes to hear from experts from relevant biomedical, biodefense, or health industries; faculty or researchers at academic institutions; health professionals, health system experts, or those who work in health care consumer organizations; or experts in state, Tribal, territorial, or local government agencies. Requests to provide remarks to the NBSB during the public meeting must be sent to *NBSB@hhs.gov* by September 15, 2022. In that request, please provide the speaker's name, title, position, and organization with a brief description of the topic that they will address. Requests to speak to the Board will be approved in consultation with the Board Chair and based on time available during the meeting. Obvious commercial bias, to include any form of advertising, marketing, or solicitation, will not be allowed.

Dawn O'Connell,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2022–16978 Filed 8–8–22; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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 would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel SARS–CoV–2 infection and genetic variations effects on Risk of Cognitive Decline.