

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 BURDEN¹

| 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.

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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.

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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.