to these regulatory provisions for efficiency of Agency operations. As a result of these cumulative changes and adjustments, the information collection reflects an overall decrease in both annual responses and burden hours.

Dated: February 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03432 Filed 2–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0895]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. COMIRNATY (COVID–19 Vaccine, mRNA) was approved on August 23, 2020, and a license was issued to BioNTech Manufacturing GmbH. FDA has determined that COMIRNATY (COVID–19 Vaccine, mRNA) meets the criteria for a material threat MCM priority review voucher, which has been issued to BioNTech Manufacturing GmbH.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, 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: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a), which was added by the Cures Act (Pub. L. 114–255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that COMIRNATY (COVID–19 Vaccine, mRNA) meets the criteria for a material threat MCM priority review voucher, which has been issued to BioNTech Manufacturing GmbH. COMIRNATY is indicated for active immunization to prevent coronavirus disease 2019 (COVID–19) caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) in individuals 16 years of age and older.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation.* For further information about COMIRNATY (COVID–19 Vaccine, mRNA) go to the Center for Biologics Evaluation and Research Approved Vaccine Products website at *https://www.fda.gov/vaccines-blood-biologics/vaccines/approved-vaccine-products.*

Dated: February 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03426 Filed 2–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0410]

Peripheral and Central Nervous System Drugs 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 Peripheral and Central Nervous System Drugs 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 take place virtually on March 30, 2022, from 10 a.m. to 4:30 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–2018–N–0410. The docket will close on March 29, 2022. Submit either electronic or written comments on this public meeting by March 29, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 29, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 29, 2022. 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 March 16, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, 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.*