

TABLE 2—CDER GUIDANCES AND COLLECTIONS—Continued

COVID-19 guidance title	CFR cite referenced in COVID-19 guidance	Another guidance title referenced in COVID-19 guidance	OMB control Nos.
		—SUPAC-SS: Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation. —SUPAC-MR: Modified Release Solid Oral Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation. —SUPAC: Manufacturing Equipment Addendum. —Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency.	

**B. CBER Guidance**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information (listed in table 3).

Therefore, clearance by OMB under the PRA (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by

OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

TABLE 3—CBER GUIDANCES AND COLLECTIONS

COVID-19 guidance title	CFR cite referenced in COVID-19 guidance	Another guidance title referenced in COVID-19 guidance	OMB control Nos.
Emergency Use Authorization for Vaccines to Prevent COVID-19 (Updated May 2021).	21 CFR 314.420 ..... 21 CFR part 312 ..... 21 CFR parts 210, 211, and 610 ..... 21 CFR part 600 ..... 21 CFR part 601 .....	Emergency Use Authorization of Medical Products and Related Authorities.	0910-0001 0910-0014 0910-0139 0910-0308 0910-0338 0910-0595

**IV. Electronic Access**

Persons with access to the internet may obtain COVID-19-related guidances at:

- FDA web page entitled “COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>.

- FDA web page entitled “Search for FDA Guidance Documents” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>; or

- <https://www.regulations.gov>.

Dated: July 16, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Neurological Disorders and Stroke; 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 of Neurological Disorders and Stroke Special

Emphasis Panel; NINDS BRAIN Review Meeting (U01 and R01 Applications).

*Date:* August 12–13, 2021.

*Time:* 10:00 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

*Contact Person:* Mir Ahamed Hossain, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Rockville, MD 20852, (301) 496-9223, [mirahamed.hossain@nih.gov](mailto:mirahamed.hossain@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: July 20, 2021.

**Tyeshia M. Roberson-Curtis,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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