Collection 3090–0300, Implementation of Information Technology Security Provision'' on your attached document.

Instructions: Please submit comments only and cite Information Collection 3090–0300, Implementation of Information Technology Security Provision, in all correspondence related to this collection. Comments received generally will be posted without change to *regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Ms. Johnnie McDowell, Program Analyst, Office of Acquisition Policy, at *gsarpolicy@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Clause 552.239–71 requires contractors, within 30 days after contract award, to submit an IT Security Plan to the Contracting Officer and Contacting Officer's Representative that describes the processes and procedures that will be followed to ensure appropriate security of IT resources that are developed, processed, or used under the contract. The clause will also require that contractors submit written proof of IT security authorization six months after contract award, and verify that the IT Security Plan remains valid annually.

B. Annual Reporting Burden

Respondents: 146.
Responses per Respondent: 2.
Total Annual Responses: 292.
Hours per Response: 5.
Total Burden Hours: 1,460.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the GSAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

OBTAINING COPIES OF PROPOSALS: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 3090–0300, Implementation of Information Technology Security Provision, in all correspondence.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2020–19870 Filed 9–8–20; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1106 and FDA–2020–D–1138]

Guidance Documents Related to Coronavirus Disease 2019; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidance documents have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances is published in the **Federal Register** on September 9, 2020. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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 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 name of the guidance document that the comments address and the docket number for the guidance (see table 1). Received comments will be placed in the docket(s) 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.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of these guidances to the address noted in table 1. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Kimberly Thomas, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993–0002, 301–796–2357; or Erica Takai, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, (HFZ–450), Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, as a result of confirmed cases of COVID–19, and after consultation with public health officials as necessary, Alex M. Azar II, Secretary of Health and Human Services, pursuant to the authority under section 319 of the Public Health Service Act (PHS Act), determined that a PHE exists and has existed since January 27, 2020, nationwide.[1] On March 13, 2020, President Donald J. Trump declared that the COVID–19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.[2]

In the **Federal Register** of March 25, 2020 (the March 25, 2020, notice) (available at *https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf*), FDA announced procedures for making available FDA guidance documents related to the COVID–19 PHE. These procedures, which operate within FDA's established good guidance practices regulations, are intended to allow FDA to rapidly disseminate Agency recommendations and policies related to COVID–19 to industry, FDA staff, and other stakeholders. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID–19 PHE, FDA believes that prior public participation will not be feasible or appropriate before FDA implements COVID–19-related guidance documents. Therefore, FDA will issue COVID–19-related guidance documents for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C) and § 10.115(g)(2). The guidances are available at FDA's web page titled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders'' (*https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders*) and through FDA's web page titled ''Search for FDA Guidance Documents'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

The March 25, 2020, notice further stated that, in general, rather than publishing a separate NOA for each COVID–19-related guidance document, FDA intends to publish periodically a consolidated NOA announcing the availability of certain COVID–19-related guidances FDA issued during the relevant period, as included in table 1. This notice announces COVID–19-related guidances that are posted on FDA's website.

II. Availability of COVID–19-Related Guidance Documents

Pursuant to the process described in the March 25, 2020, notice, FDA is announcing the availability of the following COVID–19-related guidances:

TABLE 1—GUIDANCES RELATED TO THE COVID–19 PUBLIC HEALTH EMERGENCY

Docket No.	Center	Title of guidance	Contact information to request single copies
FDA–2020–D–1106.	Center for Drug Evaluation and Research (CDER).	Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19) (March 2020) (Updated August 7, 2020).	*druginfo@fda.hhs.gov,* Please include the docket number FDA–2020–D–1106 and complete title of the guidance in the request.
FDA–2020–D–1106.	CDER	Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (March 2020) (Updated August 7, 2020).	*druginfo@fda.hhs.gov,* Please include the docket number FDA–2020–D–1106 and complete title of the guidance in the request.

[1] On April 21, 2020, the PHE Determination was extended, effective April 26, 2020; on July 23, 2020, it was extended again, effective July 25, 2020. These PHE Determinations are available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak (March 13, 2020), available at *https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

TABLE 1—GUIDANCES RELATED TO THE COVID–19 PUBLIC HEALTH EMERGENCY—Continued

Docket No.	Center	Title of guidance	Contact information to request single copies
FDA–2020–D–1106.	CDER	Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19) (March 2020) (Updated August 7, 2020).	*druginfo@fda.hhs.gov,* Please include the docket number FDA–2020–D–1106 and complete title of the guidance in the request.
FDA–2020–D–1138.	Center for Devices and Radiological Health (CDRH).	Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (July 2020).	*CDRH-Guidance@fda.hhs.gov,* Please include the document number 20038 and complete title of the guidance in the request.

Although these guidances have been implemented immediately without prior comment, FDA will consider all comments received and revise the guidances as appropriate (see § 10.115(g)(3)).

These guidances are being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidances represent the current thinking of FDA. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

A. CDER Guidances

The guidances listed in the table below refer to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the table below. These guidances also contain a collection of information not approved under a current collection. This collection of information has been granted a PHE waiver from the PRA by the Department of Health and Human Services (HHS) on March 19, 2020, under section 319(f) of the PHS Act. Information concerning the PHE PRA waiver can be found on the HHS website at *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.*

TABLE 2—CDER GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cite(s) referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB Control No(s).
Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19)—UPDATE of guidance announced in March 2020.	27 CFR parts 20 and 21.	—Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency. —Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19). —Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing. —Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application.	0910–0045, 0910–0139, 0910–0230, 0910–0291, 0910–0340, 0910–0641, 0910–0645, 0910–0800.
Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19)—UPDATE of guidance announced in March 2020.	27 CFR parts 20 and 21.	—Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency. —Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19). —Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.	0910–0045, 0910–0139, 0910–0230, 0910–0291, 0910–0340, 0910–0641, 0910–0645.

TABLE 2—CDER GUIDANCES AND COLLECTIONS—Continued

COVID–19 guidance title	CFR cite(s) referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB Control No(s).
Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency—UPDATE of guidance announced in March 2020.	.....	—Current Good Manufacturing Practices for Finished Pharmaceuticals and Medical Gases. —Postmarketing Adverse Drug Experience Reporting. —MedWatch: Adverse Event and Product Experience Reporting System (Paper-Based). —Format and Content Requirements for Over-the-Counter Drug Product Labeling. —FDA Adverse Event and Product Experience Reports; Electronic Submissions. —Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act. —Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19). —Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19).	0910–0045, 0910–0139, 0910–0230, 0910–0291, 0910–0340, 0910–0641, 0910–0645.

B. CDRH Guidances

The guidance indicated in the table below refers to previously approved collections of information. These collections of information are subject to review by the OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the table below. This guidance also contains a new collection of information not approved under a current collection. This new collection of information has been granted a PHE waiver from the PRA by HHS on March 19, 2020, under section 319(f) of the PHS Act. Information concerning the PHE PRA waiver can be found on the HHS website at *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.*

TABLE 3—CDRH GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cites(s) referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB Control No(s).	New collection covered by PHE PRA waiver
Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (July 2020).		Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	0910–0595	
		Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization.	0910–0607	
	21 CFR parts 800, 801, and 809.	.....	0910–0485	
	21 CFR part 803	.....	0910–0437	
	21 CFR part 806	.....	0910–0359	
	21 CFR part 807, subparts A through D.	.....	0910–0625	
	21 CFR part 807, subpart E ..	.....	0910–0120	
	21 CFR part 820	.....	0910–0073	
	21 CFR part 830 and 21 CFR 801.20.	.....	0910–0720	
				Manufacturer voluntary reporting to FDA of viral transport media manufacturing capacity information.
				Manufacturer voluntary reporting to FDA of sterile phosphate buffered saline/saline manufacturing capacity information.

IV. Electronic Access

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

- The 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;*
- the 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: September 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–19883 Filed 9–8–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Disease Modifying Therapies for Chronic Lung Diseases.

Date: October 8, 2020.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209–B, Bethesda, MD 20892, (301) 827–7953, *kristen.page@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 2, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–19835 Filed 9–8–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meetings

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

The meetings 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/or contract proposals 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 Child Health and Human Development Special Emphasis Panel Completion of Ongoing MFMU Network Protocols.

Date: October 30, 2020.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Helen Huang, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Bethesda, MD 20817, (301) 435–8380, *helen.huang@nih.gov*.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Intellectual and Developmental Disabilities Research Centers [IDDRC] FY 2021 (P50).

Date: November 19–20, 2020.

Time: 8:00 a.m. to 5:00 p.m..

Agenda: To review and evaluate grant applications.

Place: National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Clayton W. Mash, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Bethesda, MD 20892, (301) 496–6866, *mashc@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program No. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: September 2, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–19833 Filed 9–8–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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

The meetings 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: Emerging Technologies and Training Neurosciences Integrated Review Group Molecular Neurogenetics Study Section.

Date: October 8–9, 2020.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mary G. Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, (301) 915–6301, *marygs@csr.nih.gov*.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section.

Date: October 8–9, 2020.

Time: 8:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.