U.S. FOOD & DRUG ADMINISTRATION

January 11, 2022

Michael Campbell
Head of Regulatory Affairs & Quality
Quotient Suisse SA
Route de Crassier 13
Eysins, VD 1262
Switzerland

Re: Revocation of EUA201083

Dear Michael Campbell:

This letter is in response to a request from Quotient Suisse SA, received December 22, 2021, that the U.S. Food and Drug Administration (FDA) terminate the MosaiQ COVID-19 Antibody Magazine – EUA201083 issued on September 25, 2020 and amended April 27, 2021 and September 23, 2021. Quotient Suisse SA decided not to continue to commercially support the MosaiQ COVID-19 Antibody Magazine.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Quotient Suisse SA has notified FDA that Quotient Suisse SA has decided not to continue to commercially support the product and requested FDA terminate the MosaiQ COVID-19 Antibody Magazine – EUA201083, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201083 for the MosaiQ COVID-19 Antibody Magazine, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the MosaiQ COVID-19 Antibody Magazine is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Dated: February 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04635 Filed 3–3–22; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1825 and FDA–2020–D–1136]

Guidance Documents Related to Coronavirus Disease 2019; Availability

AGENCY: Food and Drug Administration, 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 guidances 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 March 4, 2022.

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.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, or 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.

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, the Secretary of Health and Human Services (HHS), pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247d), determined that a PHE exists and has existed since January 27, 2020, nationwide.[1] On March 13, 2020, there was a Presidential declaration 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 (85 FR 16949) (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 guidances 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 guidances. Therefore, FDA will issue COVID–19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2)). The guidances are available on FDA's web pages entitled

[1] Secretary of Health and Human Services, ''Determination that a Public Health Emergency Exists'' (originally issued on January 31, 2020, and subsequently renewed), 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://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.* On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID–19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) Pandemic (February 24, 2021), available at *https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic.*

''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*) and ''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, FDA intends to publish periodically a consolidated NOA announcing the availability of certain COVID–19-related guidances that 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–1825	CBER	Investigational COVID–19 Convalescent Plasma (Revised January 7, 2022).	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, 1–800–835–4709 or 240–402–8010; email *ocod@fda.hhs.gov.*
FDA–2020–D–1136	CDER	COVID–19 Public Health Emergency Policy on COVID–19-Related Sanitation Tunnels (February 2022).	*druginfo@fda.hhs.gov.* Please include the docket number FDA–2020–D–1136 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. CBER Guidance

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information (listed in table 2). Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (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 2—CBER GUIDANCE AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
Investigational COVID–19 Convalescent Plasma (Updated: January 7, 2022).	21 CFR part 312	.....	0910–0014
	21 CFR parts 606 and 630	.....	0910–0116
		Form FDA 3926	0910–0814

B. CDER 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 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 guidances have been approved by OMB as listed in the following table:

TABLE 3—CDER GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB control No(s).
COVID–19 Public Health Emergency Policy on COVID–19-Related Sanitation Tunnels (February 2022).	21 CFR part 312	—Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (March 2020). —COVID–19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID–19 Related Drugs and Biological Products (May 2020).	0910–0001 0910–0014

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: February 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04637 Filed 3–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Seniors and Disasters and National Advisory Committee on Individuals With Disabilities and Disasters; Notice of Meeting

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

ACTION: Notice of meeting.

SUMMARY: The National Advisory Committee on Seniors and Disasters (NACSD) and the National Advisory Committee on Individuals With Disabilities and Disasters (NACIDD), or Committees, were established by sections 2811B and 2811C, respectively, of the Public Health Service (PHS) Act, as amended by the Pandemic and All Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019. The Committees are governed by the provisions of the Federal Advisory Committee Act (FACA) and the General Services Administration FACA Final Rule. The Committees evaluate issues and programs and provide findings, advice, and recommendations to the Secretary of HHS to support and enhance all-hazards public health and medical preparedness, response, and recovery. The NACSD provides focus on the unique needs of older adults, while the NACIDD focuses on helping HHS meet the needs of people with disabilities (PWD). The Secretary of HHS has formally delegated authority to operate the NACSD and the NACIDD to ASPR.

DATES: The NACSD and NACIDD will conduct a joint, virtual, inaugural public meeting on March 30, 2022. The newly appointed members of the two advisory committees will be sworn in as Special Government Employees, followed by presentations and discussion of challenges, opportunities, and priorities for national public health and medical preparedness, response, and recovery specific to the needs of older adults and PWD in disasters. On April 1, 2022, the NACIDD will hold a second public meeting session dedicated specifically to addressing the needs of PWD; on April 6, 2022, the NACSD will hold a second public meeting session specifically to the needs of older adults. Agendas for all meeting and meeting registration links will be available on the Committees respective web page, *https://www.phe.gov/nacsd* and *https://www.phe.gov/nacidd.*

ADDRESSES: Members of the public may attend the meetings via a toll-free phone number or Zoom teleconference, which requires pre-registration. The meeting links to pre-register will be posted on *https://www.phe.gov/nacsd* and *https://www.phe.gov/nacidd.* Members of the public may provide written comments or submit questions for consideration via email to the NACSD (*NACSD@hhs.gov*) or the NACIDD (*NACIDD@hhs.gov*). Members of the public are also encouraged to provide comments after the meetings.

FOR FURTHER INFORMATION CONTACT: Dr. Maxine Kellman, NACSD Designated Federal Official, 202–260–0447, *NACSD@hhs.gov;* Tabinda Burney, NACIDD Designated Federal Official, 202–699–1779, *NACIDD@hhs.gov.* Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS), Washington, DC.

SUPPLEMENTARY INFORMATION: The NACSD and the NACIDD invite those who are involved in or represent academia, professional groups, advocacy organizations, or U.S. state, tribal, territorial, or local government to request up to four minutes to address the committees via Zoom. Requests to provide remarks during the public meetings must be sent via email to the NACSD (*NACSD@hhs.gov*) or the NACIDD (*NACIDD@hhs.gov*) at least 15 days prior to the meeting along with a brief description of the topic. We would specifically like to request inputs from the public on challenges, opportunities, and strategic priorities for national public health and medical preparedness, response, and recovery specific to the needs of people with disabilities and/or older adults before, during, and after disasters. Presenters who are selected for the public meetings will have audio only for up to four minutes during the meeting. Slides, documents, and other presentation material sent along with the request to speak will be provided to the committee members separately. Please indicate additionally whether the presenter will be willing to take questions from the committee members (at their discretion) immediately following their presentation (for up to four additional minutes).

Dawn O'Connell,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2022–04651 Filed 3–3–22; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Collaborative Islet Transplant Registry Special Emphasis Panel.

Date: March 15, 2022.

Time: 2:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health/NIDDK, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Peter J. Kozel, Ph.D., Chief, Training and Mentored Research Section, Scientific Review Branch, Division of Extramural Activities, 6707 Democracy Blvd., Room 7009, Bethesda, MD 20892, *kozelp@mail.nih.gov*, 301–594–4721.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 1, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–04623 Filed 3–3–22; 8:45 am]

BILLING CODE 4140–01–P