request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Request

As permitted by § 486.308(e), the following hospital has requested a waiver to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located:

Renown South Meadows Medical Center d/b/a Renown Rehabilitation Hospital, Reno, Nevada, is requesting a waiver to work with:

Nevada Donor Network, Inc., 2055 E Sahara Ave., Las Vegas, NV 89104

The Hospital's Designated OPO is:

Donor Network West, 12667 Alcosta Blvd. #500, San Ramon, CA 94583

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

We will consider all comments we receive by the date specified in the **DATES** section of this document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: November 17, 2023.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–25904 Filed 11–22–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1370]

COVID–19: Developing Drugs and Biological Products for Treatment or Prevention; Guidance for Industry; 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 a final guidance for industry entitled ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs and biological products for the treatment or prevention of COVID–19. This guidance describes FDA's current recommendations for phase 2 and phase 3 trials with a focus on trial population, trial design, efficacy endpoints, safety considerations, and statistical considerations. This guidance supersedes the guidance of the same name initially issued on May 19, 2020, and reissued on February 22, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on November 24, 2023.

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 Docket No. FDA–2020–D–1370 for ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' Received comments will be placed in the docket 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 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Maria Clary, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4638, Silver Spring, MD 20993–0002, 240–402–8615; or Anne Taylor, 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:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' This guidance provides FDA's current recommendations for phase 2 and phase 3 trials with a focus on trial population, trial design, efficacy endpoints, safety considerations, and statistical considerations. The development of drugs for the treatment of Long COVID–19, preventative vaccines, and convalescent plasma are not within the scope of this guidance as these development programs raise different and additional considerations.

This guidance supersedes the guidance ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention,'' which was initially issued on May 19, 2020 (85 FR 29949), and subsequently revised and reissued on February 22, 2021. This guidance was published to support public health efforts following a declaration, under section 319 of the Public Health Service Act (PHS Act) (42 U.S.C. 247d), by the Secretary of Health and Human Services of a public health emergency related to COVID–19. In the **Federal Register** of March 13, 2023 (88 FR 15417) FDA listed certain guidance documents that FDA was revising to continue in effect for 180 days after the expiration of the COVID–19 PHE declaration, during which time FDA planned to further revise the guidances. The February 2021 guidance on development of drugs and biological products for treatment or prevention of COVID–19 is included in this list.

FDA is issuing this guidance for immediate implementation in accordance with our good guidance practices regulation (§ 10.115(g)(3) (21 CFR 10.115(g)(3))) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). Specifically, we are not seeking prior comment because although the COVID–19-related public health emergency declared under section 319 of the PHS Act has expired, SARS–CoV–2 continues to circulate, COVID–19 remains a serious health risk for some individuals, and there is a need to ensure that sponsors are aware of FDA's recommendations on the development of drugs and biological products for treatment and prevention of COVID–19. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

FDA considered comments received on the guidance and the Agency's experience with COVID–19 drug development when making revisions. Changes in this final guidance include the following: revisions to remove reference to the COVID–19 public health emergency and updates to the recommendations on trial population, trial design, efficacy endpoints, safety considerations, and statistical considerations to reflect the current scientific knowledge and state of the COVID–19 pandemic. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved 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 21 CFR parts 312 and 320 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in FDA's final guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581. The collections of information in 42 CFR part 11 have been approved under OMB control number 0925–0586.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Dated: November 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–25952 Filed 11–22–23; 8:45 am]

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