samples in the pretest and main study of the experimental phase and conjoint analysis phase.

II. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register,** but websites are subject to change over time.

1. Harris, R.J., M.L. Trusty, J.I. Bechtold, et al. ''Memory for Implied Versus Directly Stated Advertising Claims,'' *Psychology & Marketing,* vol. 6, issue 2, pp. 87–96, 1989, *https://doi.org/10.1002/mar.4220060202.*
2. Burke, R.R., W.S. DeSarbo, R.L. Oliver, et al. ''Deception By Implication: An Experimental Investigation,'' *Journal of Consumer Research,* vol. 14, issue 4, pp. 483–494, 1988, *https://doi.org/10.1086/209130.*
3. Louviere, J.J., T.N. Flynn, and A.A.J. Marley, *Best-Worst Scaling: Theory, Methods, and Applications.* Cambridge: Cambridge University Press, 2015.

Dated: December 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28093 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1136]

Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization; 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 ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' This guidance provides recommendations to sponsors on the development of monoclonal antibody products targeting SARS–CoV–2 intended for the prevention or treatment of COVID–19, including addressing the impact of emerging variants. The recommendations focus on the data and information that may be used to support a request for emergency use authorization (EUA) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance supersedes the guidance entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2, Including Addressing the Impact of Emerging Variants, During the COVID–19 Public Health Emergency'' issued on February 22, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on December 21, 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–1136 for ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' 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 § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of the 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. 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' This guidance provides recommendations to sponsors on the development of monoclonal antibody products targeting SARS–CoV–2 intended for the prevention or treatment of COVID–19. The recommendations focus on the data and information that may be used to support a request for EUA under section 564 of the FD&C Act (21 U.S.C. 360bbb–3). Specifically, the guidance discusses the manufacturing, pharmacology/toxicology, virologic, and clinical considerations to support EUA.

This guidance supersedes the guidance for industry entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2, Including Addressing the Impact of Emerging Variants, During the COVID–19 Public Health Emergency,'' which was published in February 2021. FDA issued the guidance to communicate its policy for the duration of the COVID–19 public health emergency (PHE) declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). 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 monoclonal antibody products targeting SARS–CoV–2 is included in this list.

Although circumstances have improved, SARS–CoV–2 remains in broad circulation throughout the United States. The virus has and continues to evolve over time, and in certain instances, mutations in the virus have greatly reduced the activity of monoclonal antibody therapies available for the prevention or treatment of COVID–19, resulting in vulnerable populations having limited preventative and therapeutic options. FDA retains the ability to issue an EUA under section 564 of the FD&C Act for products to treat or prevent COVID–19, so the recommendations in this guidance are still pertinent (88 FR 16644). This guidance is intended to remain in effect only for the duration of the declaration by the Secretary of HHS under section 564 of the FD&C Act effective March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic (85 FR 18250). In revising this guidance, FDA considered comments received on the 2021 guidance as well as the Agency's experience issuing COVID–19-related EUAs. In addition, editorial changes were made to improve clarity.

Given the need to ensure that sponsors are aware of our current recommendations to facilitate timely development of monoclonal antibody products targeting SARS–CoV–2, FDA is issuing this guidance for immediate implementation 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 FD&C Act (21 U.S.C. 371(h)(1)(C)(i))). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices (see § 10.115(g)(3)).

The guidance represents the current thinking of FDA on ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' 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 part 314 pertaining to new drug applications have been approved under 0910–0001. The collections of information pertaining to EUA of medical products have been approved under OMB control number 0910–0595.

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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28092 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, U.S. Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting. This meeting will be open to the public. Preregistration is required for the public to attend the meeting, provide comments, and/or distribute printed material(s) to ACMH members. Information about the meeting is available from the designated contact person and will be posted on the HHS Office of Minority Health (OMH) website: *www.minorityhealth.hhs.gov.* Information about ACMH activities can be found on the OMH website under the heading *About OMH, Committees and Working Groups.*

DATES: The ACMH meeting will be held on February 13–14, 2024 from 8:30 a.m. to 5:30 p.m. EST each day. If the Committee completes its work before 5:30 p.m., the meeting will adjourn early.

ADDRESSES: The meeting will be held at the Tower Building at 1101 Wootton Parkway, Lower Level Conference Room, Rockville, Maryland 20852 and will be accessible by webcast. Members of the public must register for the meeting by 5:00 p.m. EST on January 30, 2024. Registered webcast participants will receive webcast access information prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer,