''COVID–19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention.'' This guidance describes FDA's current recommendations regarding master protocols for trials evaluating drugs and biological products for the treatment or prevention of COVID–19. Well-designed and -conducted master protocols can accelerate drug development by maximizing the amount of information obtained from the research effort. These efficiencies are of particular importance in the setting of a public health emergency such as the current COVID–19 pandemic, where the burden of disease is high and there is a critical need for the development of therapies. This guidance focuses on the trial design and conduct as well as statistical considerations for master protocols intended to generate substantial evidence of effectiveness and adequate characterization of safety for COVID–19. Additionally, this guidance provides administrative and procedural recommendations to sponsors of master protocols for COVID–19.

In light of the public health emergency related to COVID–19 declared by the Secretary of the Department of Health and Human Services (HHS), FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment (see section 701(h)(1)(C)(i) of the FD&C Act (21 U.S.C. 371(h)(1)(C)(i)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practice statute and regulation.

This guidance is intended to remain in effect for the duration of the public health emergency related to COVID–19 declared by HHS, including any renewals made by the Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). However, the recommendations and processes described in the guidance are expected to assist the Agency more broadly in its continued efforts to assist sponsors in the clinical development of drugs for the treatment or prevention of COVID–19 beyond the termination of the COVID–19 public health emergency and reflect the Agency's current thinking on this issue. Therefore, within 60 days following the termination of the public health emergency, FDA intends to revise and replace this guidance with any appropriate changes based on comments received on this guidance and the Agency's experience with implementation.

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: Master Protocols Evaluating 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. 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 21 CFR part 312, Investigational New Drug Application, have been approved under OMB control number 0910–0014 and the collections of information required for institutional review boards and informed consent are approved under OMB control number 0910–0130.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders,* or *https://www.regulations.gov.*

Dated: June 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13394 Filed 6–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1995–D–0288 (Formerly Docket No. 95D–0052)]

Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products; 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 document entitled ''Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products.'' The guidance is intended to assist applicants and manufacturers of certain licensed biological products in determining which reporting category is appropriate for a change in chemistry, manufacturing, and controls (CMC) information to an approved biologics license application (BLA). The guidance describes general and administrative information on evaluating and reporting changes and recommendations for reporting categories based on a tiered-reporting system for specific changes. The guidance announced in this notice finalizes the draft guidance, ''Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products,'' dated December 2017 and supersedes the document entitled ''Guidance for Industry: Changes to an Approved Application: Biological Products,'' dated July 1997 (July 1997 guidance).

DATES: The announcement of the guidance is published in the **Federal Register** on June 24, 2021.

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–1995–D–0288 (Formerly Docket No. 95D–0052) for ''Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products.'' 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 the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Victoria Wagman, 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 document entitled ''Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products.'' The guidance document is intended to assist applicants and manufacturers of licensed biological products in determining which reporting category is appropriate for a change in CMC to an approved BLA as specified in § 601.12 (21 CFR 601.12). The guidance document provides applicants and manufacturers general and administrative information on evaluating and reporting changes and recommendations for reporting categories based on a tiered-reporting system for specific changes under § 601.12.

FDA issued the July 1997 guidance (62 FR 39904; July 24, 1997) to assist applicants in determining which reporting mechanism is appropriate for reporting a change to an approved application to reduce the burden on manufacturers when reporting changes and to facilitate the approval process of the change being made. FDA is updating the July 1997 guidance to accommodate advances in manufacturing and testing technology and to clarify FDA's current thinking on assessing reportable changes. The updated guidance applies to certain biological products licensed under section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)). The guidance applies to all manufacturing locations, including contract locations. The following biological products are not within the scope of this guidance: (1) Whole blood, blood components (including source plasma), and source leukocytes; (2) specified biotechnology products described in § 601.2(a); and (3) biosimilar and interchangeable products subject to licensure under section 351(k) of the PHS Act. The guidance also does not apply to human cells, tissues, and cellular and tissue-based products regulated solely under section 361 of the PHS Act (42 U.S.C. 264) and the regulations in 21 CFR part 1271.

In the **Federal Register** of December 22, 2017 (82 FR 60750), FDA announced the availability of the draft guidance of the same title dated December 2017. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance was updated to reflect the ICH Harmonised Guideline: Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management: Q12, which was issued after publication of the draft guidance on November 11, 2019. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated December 2017. The guidance also supersedes the July 1997 guidance.

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 ''Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products.'' 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. 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 21 CFR part 210 and 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR 601.12 have been approved under OMB control numbers 0910–0338, and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *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: June 15, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–13392 Filed 6–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0512]

Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the following public workshop entitled ''Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs.'' The purpose of the public workshop is to discuss the challenges and clinical trial design considerations for developing therapeutic products for the treatment of progressive multifocal leukoencephalopathy (PML).

DATES: The public workshop will be held virtually on September 21, 2021, from 10 a.m. to 4:15 p.m., Eastern Time. Submit either electronic or written comments on this public workshop by November 1, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in virtual format only.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 1, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 1, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2021–N–0512 for ''Considerations for Progressive Multifocal Leukoencephalopathy Clinical Trial Designs.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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