apply to: (1) statutory and regulatory standards that are legally binding, such as certain provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and the Public Health Service Act (42 U.S.C. 6A); (2) standards developed by Standards Development Organizations that do not follow consensus mechanisms; or (3) electronic data exchange standards for submissions to CBER.

In the **Federal Register** of Thursday, June 16, 2022 (87 FR 36327), FDA announced the availability of the draft guidance of the same title dated June 2022. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes minor edits to improve clarity and the addition of information regarding information collection provisions under the Paperwork Reduction Act of 1995. The guidance announced in this notice finalizes the draft guidance dated June 2022.

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 ''Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies.'' 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

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *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: October 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23156 Filed 10–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1137]

Development and Licensure of Vaccines To Prevent COVID–19; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a revised guidance for industry entitled ''Development and Licensure of Vaccines to Prevent COVID–19.'' This guidance revises the guidance of the same name, which was announced in the **Federal Register** on August 3, 2020. FDA is issuing this guidance to assist the Agency and sponsors in the clinical development and licensure of vaccines for the prevention of COVID–19. Additionally, this guidance provides an overview of key considerations to satisfy regulatory requirements set forth in the investigational new drug application (IND) regulations and in the licensing regulations for chemistry, manufacturing, and controls (CMC), and nonclinical and clinical data through development and licensure, and for post-licensure safety evaluation of COVID–19 preventive vaccines. FDA is also announcing the withdrawal of an FDA guidance document related to COVID–19.

DATES: The announcement of the guidance is published in the **Federal Register** on October 20, 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–1137 for ''Development and Licensure of Vaccines to Prevent COVID–19.'' 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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. 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: Jessica Gillum, 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

We are announcing the availability of a revised guidance for industry entitled ''Development and Licensure of Vaccines to Prevent COVID–19.'' The recommendations described in the guidance are expected to assist the Agency and sponsors in the clinical development and licensure of vaccines for the prevention of COVID–19.

Due to the COVID–19 public health emergency, there was an urgent need to develop safe and effective vaccines to prevent COVID–19 and work collaboratively with industry and other partners to accelerate those efforts. To help address those needs, in June 2020, FDA issued a guidance entitled ''Development and Licensure of Vaccines to Prevent COVID–19'' (the ''June 2020 guidance'') to assist sponsors in the clinical development and licensure of vaccines for the prevention of COVID–19. The June 2020 guidance, which was announced in the **Federal Register** on August 3, 2020 (85 FR 46641), explained that we expected the recommendations would continue to apply outside the context of the COVID–19 public health emergency, and that FDA would replace that guidance with any appropriate changes based on public comments and our experience with implementation. In addition, in the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed the June 2020 guidance as one of the guidances the Agency was revising to continue in effect for 180 days after the COVID–19 public health emergency declaration issued under the Public Health Service Act expired on May 11, 2023, during which time FDA planned to further revise those guidances. Consistent with what we said in the **Federal Register** of March 13, 2023, FDA is issuing this revised final guidance.

We are issuing this revised guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)). We made this determination because the revisions to the guidance acknowledge the current epidemiology of COVID–19 or reflect current recommendations provided to sponsors and immediate implementation is required to facilitate the development of vaccines to protect the public health. Specifically, we are issuing this guidance to ensure that sponsors are aware of our current recommendations to expedite the timely development of vaccines to prevent COVID–19. In addition, we note that interested parties have had the opportunity to comment on the June 2020 guidance. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA's GGP regulation (§ 10.115(g)(3)(D)).

The revised guidance provides an overview of key considerations to satisfy regulatory requirements set forth in the IND regulations in part 312 (21 CFR part 312) and licensing regulations in part 601 (21 CFR part 601) for CMC, and nonclinical and clinical data through development and licensure, and for post-licensure safety evaluation of COVID–19 preventive vaccines. FDA is committed to supporting all scientifically sound approaches to attenuating the clinical impact of COVID–19. There are many candidate COVID–19 vaccines currently in development, and FDA recognizes that the considerations presented do not represent all the considerations necessary to satisfy statutory and regulatory requirements applicable to the licensure of vaccines intended to prevent COVID–19. The nature of a particular vaccine and its intended use may impact specific data needs.

We received numerous comments on the June 2020 guidance. Those comments were considered and the revisions in this guidance reflect the responses to the comments as appropriate. Changes to the guidance from the June 2020 guidance include removal of reference to the COVID–19 public health emergency and revisions to the nonclinical data section to take into consideration that enhanced respiratory disease has not occurred with clinical use of COVID–19 vaccines. The clinical trials section has been revised to reflect that at this stage of the pandemic only very young children are likely to be serologically naïve and, in recognition of the available data on vaccine effectiveness, to recommend that sponsors provide appropriate justification for statistical criteria for clinical disease efficacy studies. In addition, editorial changes were made to improve clarity. The revised guidance announced in this notice replaces the June 2020 guidance.

The revised guidance represents the current thinking of FDA on the development and licensure of vaccines to prevent COVID–19. 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 part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 58 regarding good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119; the collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR parts 210, 211 and 610 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 600 have been approved under OMB control

numbers 0910–0308 and 0910–0291 (Form FDA 3500A); the collections of information in part 601 have been approved under OMB control number 0910–0338; the collections of information in FDA's guidance entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581; and, the collections of information in FDA's guidance entitled ''Emergency Use Authorization of Medical Products and Related Authorities'' have been approved under OMB control number 0910–0595.

III. Emergency Use Authorization for Vaccines To Prevent COVID–19 Guidance

In October 2020, FDA first issued a guidance entitled ''Emergency Use Authorization for Vaccines to Prevent COVID–19'' (Vaccine EUA guidance) to provide sponsors of requests for emergency use authorization (EUA) for COVID–19 vaccines with recommendations regarding the data and information needed to support the issuance of an EUA under section 564 of the FD&C Act (21 U.S.C. 360bbb–3) for an investigational vaccine to prevent COVID–19. Although, the guidance stated that it was intended to remain in effect only for the duration of the public health emergency related to COVID–19 declared under the Public Health Service Act, in the **Federal Register** of March 13, 2023 (88 FR 15417 at 15421), FDA listed the guidance as one of the COVID–19-related guidances the Agency was revising to continue in effect for 180 days after the COVID–19 public health emergency declared under the PHS Act expired on May 11, 2023, during which time FDA planned to further revise those guidances. However, circumstances have changed since the end of the declared public health emergency on May 11, 2023. FDA has reviewed the Vaccine EUA guidance and determined that the guidance is no longer needed, as the Agency has shifted its focus toward communicating directly with individual manufacturers. Accordingly, the EUA guidance will no longer be in effect after the publication of the guidance for immediate implementation announced in this notice, ''Development and Licensure of Vaccines to Prevent COVID–19.''

IV. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23162 Filed 10–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2316]

Benefit-Risk Assessment for New Drug and 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 for industry entitled ''Benefit-Risk Assessment for Human Drug and Biological Products.'' FDA has developed this guidance document in accordance with goals associated with the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI) under Title I of the FDA Reauthorization Act of 2017 and requirements under the 21st Century Cures Act. The intent of this guidance is to provide drug sponsors and other stakeholders with better clarity on how considerations about a drug's benefits, risks, and risk management options factor into FDA's pre- and postmarket regulatory decisions about new drug applications (NDAs) or biologics license applications (BLAs). This guidance finalizes the draft guidance of the same title issued in September 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on October 20, 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–2316 for ''Benefit-Risk Assessment for New Drug and 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