from cattle, as well as, with regard to §§ 189.5(e) and 700.27(e), foreign governments seeking designation under those regulations.

In the **Federal Register** of August 11, 2023 (88 FR 54617), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment that was not related to the PRA and therefore will not be addressed in this document.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
189.5(c)(6) and 700.27(c)(6); affirmation of compliance.	54,825	1	54,825	0.033 (2 minutes)	1,809
189.5(e) and 700.27(e); request for designation.	1	1	1	80	80
189.5(e) and 700.27(e); response to request for review by FDA.	1	1	1	26	26
Total					1,915

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Domestic Facilities	697	52	36,244	0.25 (15 minutes)	9,061
Foreign Facilities	916	52	47,632	0.25 (15 minutes)	11,908
Total					20,969

[1] There are no capital or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: January 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01586 Filed 1–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6827]

Advisory Committee; Vaccines and Related Biological Products Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Vaccines and Related Biological Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Vaccines and Related Biological Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the December 31, 2025, expiration date.

DATES: Authority for the Vaccines and Related Biological Products Advisory Committee will expire on December 31, 2025, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Sussan Paydar, Division of Scientific Advisors and Consultants, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 202–657–8533, *Sussan.Paydar@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Vaccines and Related Biological Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective vaccines and related biological products for human use, and as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and as required, any other products for which FDA has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner.

Pursuant to its charter, the Committee shall consist of a core of 15 voting members, including the Chairperson (the Chair). Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, hypersensitivity reactions to the vaccines, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. Members will be invited

to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. Ex Officio voting members, one each from the Department of Health and Human Services, the Centers for Disease Control and Prevention, and the National Institutes of Health, may be included. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one nonvoting member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional nonvoting representative of consumer interests and a nonvoting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/charter-vaccines-and-related-biological-products-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: January 23, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–01585 Filed 1–25–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0810]

Conducting Remote Regulatory Assessments—Questions and Answers; Revised Draft 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 for comment of a revised draft guidance for industry entitled ''Conducting Remote Regulatory Assessments—Question and Answers.'' FDA has revised and is reissuing the draft guidance in response to public comments and recent amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act). When finalized, this guidance will describe FDA's current thinking regarding its use of remote regulatory assessments (RRAs). FDA has used RRAs to conduct oversight, mitigate risk, meet critical public health needs, and help maximize compliance of FDA-regulated products. This revised draft guidance provides answers to frequently asked questions regarding RRAs.

DATES: Submit either electronic or written comments on the draft guidance by March 26, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2022–D–0810 for ''Conducting Remote Regulatory Assessments; Questions and Answers; Guidance for Industry.'' 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