additional 2 years beyond the charter expiration date. The new charter will be in effect until December 31, 2021.

DATES: Authority for the Vaccines and Related Biological Products Advisory Committee will expire on December 31, 2021, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Prabhakara Atreya, Division of Scientific Advisors and Consultants, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993–0002, 240–402–8006, *Prabhakara.Atreya@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3, 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 that 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, allergy, 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 non-voting 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, a non-voting representative of consumer interests and a non-voting 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/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm129571.htm* 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 document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: January 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01988 Filed 1–31–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0719]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 4, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0675. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

OMB Control Number 0910–0675—Extension

This information collection supports recommendations found in Agency guidance. Specifically, we have developed guidance intended to encourage manufacturers of drug and therapeutic biological products, and any raw materials and components used in those products, to develop a written Emergency Plan (Plan) for maintaining an adequate supply of medically necessary drug products (MNPs) during an emergency that results in high employee absenteeism. The guidance entitled, ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products,'' discusses the elements that should be covered by such a Plan, and is available from our website at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/planning-effects-high-absenteeism-ensure-availability-medically-necessary-drug-products.*

In the **Federal Register** of October 25, 2019 (84 FR 57448), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Activate/deactivate Plan as recommended in the guidance	2	1	2	16	32

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Develop initial Plan as recommended in the guidance	70	1	70	250	17,500

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

As explained in the guidance, we provide recommendations for developing and implementing a written Plan, including: (1) Identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate the Plan and make decisions during the emergency; (2) prioritizing the manufacturer's drug products based on medical necessity; (3) identifying actions that should be taken prior to an anticipated period of high absenteeism; (4) identifying criteria for activating the Plan; (5) performing quality risk assessments to determine which manufacturing activities may be reduced to enable the company to meet a demand for MNPs; (6) returning to normal operations and conducting a post-execution assessment of the execution outcomes; and (7) testing the Plan.

The guidance also encourages manufacturers to include and document procedures in the Plan for notifying the FDA Center for Drug Evaluation and Research (CDER) when the Plan is activated and when returning to normal operations. The guidance recommends that these notifications occur within 1 day of a Plan's activation and within 1 day of a Plan's deactivation. The guidance identifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products' manufacturing will be temporarily delayed, and any anticipated or potential drug shortages. We assume two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be submitted to CDER annually, and assume each notification requires 16 hours to prepare and submit.

Finally, the guidance recommends developing a Plan for each individual manufacturing facility as well as a broader Plan that addresses multiple sites within the organization. For purposes of this information collection analysis, we consider the Plan for an individual manufacturing facility and the broader Plan to comprise one Plan for each manufacturer. Based on available data on the number of manufacturers that would be covered by the guidance, we previously estimated 70 manufacturers will develop a Plan as recommended by the guidance (*i.e.,* one Plan per manufacturer, to include all manufacturing facilities, sites, and drug products) and that each Plan would take approximately 500 hours to develop. Upon development of the plan, however, we believe fewer hours are necessary to maintain and update it as needed. As FDA issued the guidance in 2011, we now assume that most respondents have developed the recommended plan, and therefore we limit our current burden estimate to updates and maintenance. Accordingly, we have reduced our estimate by half, reasoning that, although it takes fewer hours for updates and maintenance, new respondents may choose to adopt recommendations found in the guidance.

Dated: January 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01992 Filed 1–31–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1072]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of