U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The Administration for Community Living (ACL) is requesting approval for a revised data collection associated with the Evaluation of the Administration for Community Living's (ACL) American Indian, Alaska Natives, and Native Hawaiian Programs (Older Americans Act [OAA] Title VI; short title: Evaluation of the Title VI Programs). OAA Title VI establishes grants to Native Americans for nutrition services, supportive services, and family caregiver support services. The purpose of Title VI is ''to promote the delivery of supportive services, including nutrition services, to American Indians, Alaskan Natives, and Native Hawaiians that are comparable to services provided under Title III'' (42 U.S.C. 3057), which provides nutrition, caregiver and supportive services to the broader U.S. population. Title VI is comprised of three parts; Part A provides nutrition and supportive services to American Indians and Alaska Natives, Part B provides nutrition and supportive services to Native Hawaiians, and Part C provides caregiver services to any programs that have Part A/B.

The evaluation will consist of six data collection activities: (1) Tribal program staff interviews; (2) tribal program staff focus groups, (3) tribal elder focus groups, (4) tribal elder interviews, (5) tribal caregiver focus groups, and (6) follow-up tribal program staff interview.

ACL is requesting to revise the currently approved data collection under OMB 0985–0059 by removing the caregiver survey and adding a follow-up tribal program staff interview. The proposed revisions also include removing annual performance reporting data elements from the currently approved IC under OMB 0985–0059 to the OMB approved Title VI Annual Performance Report under OMB 0985–0007.

For review and comment on this proposed information collection request, please visit the ACL website *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows:

Respondent type	Form name	Number of annual respondents	Number of responses per respondent	Average burden per response (in hours)	Annual burden hours
Program director	Program staff interview guide	12	1	1	12
Program director	Program staff focus group moderator guide	12	1	2	24
Program director	Program staff follow-up interview guide	12	1	1	12
Other Program Staff	Tribal program staff interview guide	12	1	1	12
Other Program Staff	Tribal program staff focus group moderator guide.	12	1	2	20
Tribal elder	Tribal elder focus group moderator guide	100	1	2	200
Tribal elder	Tribal elder interview guide	20	1	1	20
Caregiver	Tribal caregiver focus group moderator guide	87	1	2	174
Total		267			474

Dated: May 12, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–10671 Filed 5–18–20; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1370]

COVID–19: Developing Drugs and Biological Products for Treatment or Prevention; 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 ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' This guidance describes FDA's current recommendations regarding phase 2 or phase 3 trials for drugs or biological products under development for the treatment or prevention of COVID–19. Given the public health emergency presented by COVID–19, this guidance document is being implemented without prior public comment because FDA has determined that prior public participation is not feasible or appropriate, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on May 19, 2020. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

ADDRESSES: You may submit 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–1370 for ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' 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.

• 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.

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 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; or 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 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: Eithu Lwin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–0728; or Stephen Ripley, 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 guidance for industry entitled ''COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.'' There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named SARS–CoV–2, and the disease it causes has been named Coronavirus Disease 2019 (COVID–19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID–19 and mobilized the Operating Divisions of HHS. The public health emergency declaration was renewed on April 21, 2020. In addition, on March 13, 2020, the President declared a national emergency in response to COVID–19.

This guidance describes FDA's current recommendations regarding phase 2 or phase 3 trials for drugs under development to treat or prevent COVID–19. This guidance focuses on the patient population, trial design, efficacy endpoints, safety considerations, and statistical considerations for such trials. Drugs should have undergone sufficient development before their evaluation in phase 2 or phase 3.

This guidance focuses on the development of drugs with direct antiviral activity or immunomodulatory activity. However, the recommendations in this guidance may be applicable to development plans for drugs for COVID–19 with other mechanisms of action. The mechanism of action of the drug may impact key study design elements (*e.g.,* population, endpoints, safety assessments, duration of followup, etc.).

Preventative vaccines are not within the scope of this guidance. Nor does this guidance provide general recommendations on early drug development in COVID–19, such as use of animal models.

In light of the public health emergency related to COVID–19 declared by the Secretary of 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 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: Developing 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

The 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 (PRA) (44 U.S.C. 3501–3521). Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR parts 312 and 320 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 parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 320 have been approved under OMB control number 0910–0291; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in FDA's draft guidance for industry entitled ''Formal Meetings Between FDA and Sponsors and Applicants of Prescription Drug User Fee Act Products'' have been approved under OMB control number 0910–0429; the collections of information in FDA's final guidance for clinical trial sponsors 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 final guidance for industry entitled ''Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring'' have been approved under OMB control number 0910–0733.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, or https://www.regulations.gov.*

Dated: May 13, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10635 Filed 5–18–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a virtual meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held on Tuesday, June 9, 2020. If needed, additional sessions and may be added on Wednesday, June 10, 2020. The confirmed meeting times and agenda will be posted on the NVAC website at *http://www.hhs.gov/nvpo/nvac/meetings/index.html* as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at: *http://www.hhs.gov/nvpo/nvac/meetings/index.html* at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting or participate in public comment. Please register at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, at the Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Mary E. Switzer Building, Room L618, 330 C Street SW, Washington, DC 20024. Email: *nvac@hhs.gov.* Telephone: 202–795–7611.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During the June 2020 NVAC meeting, sessions will focus on coronavirus vaccine development, reimbursement and changes in billing and coverage with updates from members. Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: *http://www.hhs.gov/nvpo/nvac/index.html.*

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit written comments. Written comments should not exceed three pages in length. Individuals submitting written comments should email their comments