

propose a legislative priority project should include the priority area(s) in the project goal, all objectives and indicators as reflected in the project's framework, project approach, Objective Work Plan and Outcome Tracker. Reviewers should provide 10 points if all elements are included in the application to address one or more of the economic development priority areas.

In addition, during tribal consultation, additional social development priorities areas were identified by Native communities to potentially fund through the SEDS program. Therefore, 5 bonus points will be awarded to applications that address one or more of the following Native community priority areas: Native Veterans, Missing and Murdered Native Americans (MMNA), or Emergency Preparedness and Response. Applications that address one or more of these priorities areas should include the priority area in the project goal, all objectives, indicator(s), and target population (either as participants or beneficiaries). Reviewers should provide 5 points if all elements are included in the application to address one or more priority areas. Since social and economic development projects have different project goals, no application will be eligible to receive both sets of bonus points. In addition, the SEDS program areas of interest will be expanded to include MMNA and Anti-Human Trafficking.

7. Changes to SEDS-AK FOA—Section 803 of NAPA, 42 U.S.C. 2991b. ANA will also incorporate the new legislative economic development priorities into the SEDS-AK FOA. Therefore, new program areas of interest for SEDS-AK will include the following: (1) The development of a Tribal code or court system for purposes of economic development, including commercial codes, training for court personnel, and the development of nonprofit subsidiaries or other tribal business structures; (2) the development of native community development financial institutions, including training and administrative expenses; (3) the development of a tribal master plans for community and economic development and infrastructure. Therefore, 10 bonus points will be awarded to applications that address one or more of these priority areas. Applications that propose a legislative priority project should have it included in the project goal, all objectives and indicators as reflected in the project's framework, the project approach, and the Objective Work Plan and Outcome Tracker. Reviewers should provide 10 points if all elements are

included in the application to address one or more of the economic development priority areas. In addition, ANA plans to modify the description of the program purpose for the SEDS-AK FOA to provide a competitive advantage for smaller Alaska Native villages or organizations that have never received ANA funding. Therefore, the FOA will state that reviewers should award 5 bonus points in the scoring criteria if an eligible entity has never received an ANA award. ANA staff will confirm during the objective review process if an applicant organization for SEDS-AK has received a past ANA award.

8. Changes to EMI FOA—Section 803C of NAPA, 42 U.S.C. 2991b–3. In accordance with 42 U.S.C. 2991b–3(c)(7), applicants for an EMI grant must submit an official document that certifies the applicant has at least 3 years of experience in operating and administering a Native American language survival school, a Native American language nest, or any other educational program in which instruction is conducted in a Native American language, in accordance with Public Law 109–394. Therefore, the EMI FOA will have a new evaluation criterion to score 10 points to ensure the application includes a certification document that demonstrates the applicant has at least 3 years of experience in operating a language nest, survival school, or other native language educational program. As a result, the EMI FOA's scoring criteria will change as follows:

Approach for a maximum of 75 points, to consist of the following: Nest or Survival School Certification (10 points); Long Term Community Goal (2 points); Current Community Condition (3 points); Project Goal (2 points); Objectives (6 points); Outcomes and Indicators (5 points); Outputs (3 points); Outcome Tracker and Outcome Tracking Strategy (7 points); Community-Based Strategy (8 points); Readiness and Implementation Strategy (16 points); and the Objective Work Plan (OWP) (13 points).

Organizational Capacity for a maximum of 10 points.

Budget and Budget Justification for a maximum of 15 points, to consist of the following: Line Item Budget (5 points) and Budget Justification (10 points).

9. Changes to SEDS-GO FOA—Sections 803 and 803B of NAPA, 42 U.S.C. 2991b; 2991b–2. In FY 2020, ANA introduced a new FOA as a special initiative under the SEDS program to support growing organizations to provide funding to enhance their internal capacity and infrastructure to better serve their members or their

communities. There will be no substantive changes to application requirements in the FY 2021 SEDS-GO FOA. There will be slight changes to the evaluation scoring criteria, which will be as follows:

Approach (for a maximum of 70 points) to consist of the following: Introduction to the Applicant Organization (6 points); Targeted Challenge (6 points); Project Goal (6 points); SMART Objectives (6 points); Outcomes and Indicators (6 points); Description of Project Implementation Strategy (25 points); Objective Work Plan (OWP) (15 points).

Organizational Capacity—15 points.

Budget and Budget Justification (for a maximum of 15 points) to consist of a Line Item Budget (5 points) and a Budget Justification (10 points).

Bonus Points—5 bonus points may be provided to applicants that have never received an ANA grant award.

Statutory Authority: Section 814 of the Native American Programs Act of 1974, as amended.

Elizabeth Leo,

Senior Grant Policy Specialist, Office of Administration, Administration for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1136]

Guidance Documents Related to Coronavirus Disease 2019; 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 FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances is published in the **Federal Register** on February 19, 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 name of the guidance document that the comments address and the docket number for the guidance (see table 1). Received comments will be placed in the docket(s) 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 § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of these guidances to the address noted in table 1. 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.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, Kimberly Thomas, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993-0002, 301-796-2357, or Erica Takai, Center for Devices and Radiological Health

(CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, as a result of confirmed cases of COVID-19, and after consultation with public health officials as necessary, the Secretary of Health and Human Services (HHS), pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247d), determined that a PHE exists and has existed since January 27, 2020, nationwide.¹ On March 13, 2020, there was a Presidential declaration that the COVID-19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.²

In the **Federal Register** of March 25, 2020 (85 FR 16949) (the March 25, 2020, notice) (available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>), FDA announced procedures for making available FDA guidances related to the COVID-19 PHE. These procedures, which operate within FDA's established good guidance practices regulations, are intended to allow FDA to rapidly disseminate Agency recommendations and policies related to COVID-19 to industry, FDA staff, and other stakeholders. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID-19 PHE, FDA believes that prior public participation will not be feasible or appropriate before FDA implements COVID-19-related guidances. Therefore, FDA will issue COVID-19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2)). The guidances are available on FDA's web pages entitled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders" (available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other>).

¹ Secretary of Health and Human Services, "Determination that a Public Health Emergency Exists" (originally issued on January 31, 2020, and subsequently renewed), available at: <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (March 13, 2020), available at: <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

stakeholders) and “Search for FDA Guidance Documents” (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>).

The March 25, 2020, notice further stated that, in general, rather than publishing a separate NOA for each COVID-19-related guidance, FDA

intends to publish periodically a consolidated NOA announcing the availability of certain COVID-19-related guidances that FDA issued during the relevant period, as included in table 1. This notice announces COVID-19-related guidances that are posted on FDA’s website.

II. Availability of COVID-19-Related Guidance Documents

Pursuant to the process described in the March 25, 2020, notice, FDA is announcing the availability of the following COVID-19-related guidances:

TABLE 1—GUIDANCES RELATED TO THE COVID-19 PUBLIC HEALTH EMERGENCY

Docket No.	Center	Title of guidance	Contact information to request single copies
FDA-2020-D-1825	CBER	Investigational COVID-19 Convalescent Plasma (Updated January 2021).	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010; email ocod@fda.hhs.gov .
FDA-2020-D-1137	CBER	Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID-19 Public Health Emergency (January 2021).	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, 1-800-835-4709 or 240-402-8010; email ocod@fda.hhs.gov .
FDA-2020-D-1136	CDER	Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency (December 2020).	druginfo@fda.hhs.gov . Please include the docket number FDA-2020-D-1136 and complete title of the guidance in the request.
FDA-2020-D-1136	CDER	Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency (January 2021).	druginfo@fda.hhs.gov . Please include the docket number FDA-2020-D-1136 and complete title of the guidance in the request.
FDA-2020-D-1136	CDER	COVID-19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS-CoV-2 Infectivity (January 2021).	druginfo@fda.hhs.gov . Please include the docket number FDA-2020-D-1136 and complete title of the guidance in the request.
FDA-2020-D-1138	CDRH	Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (January 2021).	CDRH-Guidance@fda.hhs.gov . Please include the document number 20041-R1 and complete title of the guidance in the request.

Although these guidances have been implemented immediately without prior comment, FDA will consider all comments received and revise the guidances as appropriate (see § 10.115(g)(3)).

These guidances are being issued consistent with FDA’s good guidance practices regulation (§ 10.115). The guidances represent the current thinking of FDA. They do not establish any rights for any person and are not binding on

FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

A. CBER Guidances

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information (listed in table 2).

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 these guidances. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

TABLE 2—CBER GUIDANCES AND COLLECTIONS

COVID-19 guidance title	CFR cite referenced in COVID-19 guidance	Another guidance title referenced in COVID-19 guidance	OMB control No(s).
Investigational COVID-19 Convalescent Plasma; Guidance for Industry (Updated: January 15, 2021).	21 CFR part 312, 21 CFR parts 606 and 630.	Form FDA 3926	0910-0014, 0910-0116, 0910-0814.
Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID-19 Public Health Emergency (January 2021).	21 CFR 1271.50, 21 CFR part 211, 21 CFR part 312 (INDs), 21 CFR part 601 (BLAs), 21 CFR 314.420 (Master Files).	0910-0543, 0910-0139, 0910-0014, 0910-0338, 0910-0001.

B. CDER Guidances

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information (listed in table 3).

Therefore, clearance by OMB under the PRA (44 U.S.C. 3501–3521) is not required for these guidances. The previously approved collections of information are subject to review by

OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

TABLE 3—CDER GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID–19 Public Health Emergency (December 2020).	21 CFR 314.3(b), 21 CFR 600.3 and 600.21, 21 CFR 601.20(d).	Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID–19 Public Health Emergency: Questions and Answers.	0910–0001, 0910–0338, 0910–0139.
Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID–19 Public Health Emergency.	21 CFR 50, 21 CFR 312, 21 CFR 314.3, 21 CFR 314.101, 21 CFR 314.105, 21 CFR 320.1, 21 CFR 320.23(b), 21 CFR 320.24–26, 21 CFR 320.31, 21 CFR 314.94, 314.101, 314.105.	Referencing Approved Drug Products in ANDA Submissions. Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application. Conduct of Clinical Trials of Medical Products during the COVID–19 Public Health Emergency. ANDA Submissions—Content and Format of Abbreviated New Drug Application. Controlled Correspondence Related to Generic Drug Development. Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA. Use of Electronic Informed Consent in Clinical Investigations—Questions and Answers. Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring.	0910–0001, 0910–0014, 0910–0130, 0910–0139, 0910–0303, 0910–0572, 0910–0755, 0910–0797.
COVID–19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS–CoV–2 Infectivity.	21 CFR 211.165, 21 CFR 211.194, 21 CFR 601.2, 21 CFR 610.3, 21 CFR 610.10.	ICH guidance for Industry Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products. Analytical Procedures and Methods Validation for Drugs and Biologics. ICH guidance for industry Q2(R1) Validation of Analytical Procedures: Text and Methodology. Emergency Use Authorization of Medical Products and Related Authorities. Bioanalytical Method Validation. ICH guidance for industry M4Q: The CTD—Quality. ICH guidance for industry Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products. ICH guidance for industry Q8(R2) Pharmaceutical Development.	0910–0001, 0910–0014, 0910–0338, 0910–0139, 0910–0303.

C. CDRH Guidance

While this guidance contains no collection of information, it does refer to previously approved FDA collections of

information (listed in table 4). Therefore, clearance by OMB under the 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 the following FDA regulations have been approved by OMB as listed in the following table:

TABLE 4—CDRH GUIDANCE AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (January 2021).	800, 801, and 809 807, subparts A through D 807, subpart E 803 806 820	0910–0485. 0910–0625. 0910–0120. 0910–0437. 0910–0359. 0910–0073.

IV. Electronic Access

Persons with access to the internet may obtain COVID–19-related guidances at:

- FDA web page entitled “COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>;
- FDA web page entitled “Search for FDA Guidance Documents” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>; or
- <https://www.regulations.gov>.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA–2020–N–2253]

Medical Device User Fees; Stakeholder Meetings on Medical Device User Fee Amendments of Fiscal Years 2023 to 2027 Reauthorization; Request for Notification of Stakeholder Intention to Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders—including patient and

consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Medical Device User Fee Amendments (MDUFA). The statutory authority for MDUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting user fees for the medical device program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next MDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA’s negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent public stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by February 26, 2021. Stakeholder meetings will be held monthly. It is anticipated that they will commence in March 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The meetings will take place virtually and will be held by webcast only. Submit notification of intention to participate in monthly stakeholder meetings by email to MDUFARReauthorization@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Ellen Olson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1664, Silver Spring, MD 20993, 301–796–4322, MDUFARReauthorization@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of MDUFA. MDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of medical devices. The authorization for the current program (MDUFA IV) expires in September 2022. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the medical device review process.

Section 738A(b)(1) of the FD&C Act (21 U.S.C. 379j–1(b)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts, in developing recommendations for the next MDUFA program. FDA initiated the reauthorization process by holding a public meeting on October 27, 2020, where stakeholders and other members of the public were given an opportunity to present their views on the reauthorization. The FD&C Act further requires that FDA continue meeting with the representatives of patient and consumer advocacy groups at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization and their suggestions for changes. It is anticipated that these monthly stakeholder consultation meetings will commence in March 2021.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer advocacy groups, healthcare professional associations, as well as