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 of 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—Approach for a maximum of 75 points, to consist of 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 plan 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, 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, 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:

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).

Organizational Capacity—15 points.

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 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.

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.regulations.gov.

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. 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, 2020.1

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.


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

<table>
<thead>
<tr>
<th>Docket No.</th>
<th>Center</th>
<th>Title of guidance</th>
<th>Contact information to request single copies</th>
</tr>
</thead>
</table>

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 Guidelines**

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**

|-------------------------|------------------------------------------|-------------------------------------------------------|--------------------|
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>
<thead>
<tr>
<th>COVID–19 guidance title</th>
<th>CFR cite referenced in COVID–19 guidance</th>
<th>Another guidance title referenced in COVID–19 guidance</th>
<th>OMB control No(s.)</th>
</tr>
</thead>
</table>
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

<table>
<thead>
<tr>
<th>COVID–19 guidance title</th>
<th>CFR cite referenced in COVID–19 guidance</th>
<th>Another guidance title referenced in COVID–19 guidance</th>
<th>OMB control No(s.)</th>
</tr>
</thead>
</table>

IV. Electronic Access

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

- FDA web page entitled “Search for FDA Guidance Documents” available at https://www.fda.gov/监管信息/搜索fda指导文件; or


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-03421 Filed 2–18–21; 8:45 am]

BILLING CODE 4164–01–P

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 MDUFAVReauthorization@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. MDUFAVReauthorization@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