Human Services to serve four-year terms. New members are selected each year to replace those members who are completing their appointments.

The USPSTF rigorously evaluates the effectiveness of clinical preventive services and formulating or updating recommendations regarding the appropriate provision of preventive services. Current USPSTF recommendations and associated evidence reviews are available on the internet (*www.uspreventiveservices taskforce.org*).

USPSTF members meet three times a year for two days in the Washington, DC area or virtually if necessary. A significant portion of the USPSTF's work occurs between meetings during conference calls and via email discussions. Member duties include prioritizing topics, designing research plans, reviewing and commenting on systematic evidence reviews, discussing evidence and making recommendations on preventive services, reviewing stakeholder comments, drafting final recommendation documents, and participating in workgroups on specific topics and methods. Members can expect to receive frequent emails, can expect to participate in multiple conference calls each month, and can expect to have periodic interaction with stakeholders. AHRQ estimates that members devote approximately 250 hours a year outside of in-person meetings to their USPSTF duties. The members are all volunteers and do not receive any compensation beyond support for travel to attend the thrice yearly meetings and trainings.

Dated: December 27, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–28870 Filed 1–2–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5653]

Food and Drug Administration's Draft Report and Plan on Best Practices for Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability, request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Food and Drug Administration's Draft Report and Plan on Best Practices for Guidance.'' This draft report responds to the Consolidated Appropriations Act of 2023, which directs FDA to issue a report identifying best practices for the efficient prioritization, development, issuance, and use of guidance documents and a plan for implementation of such best practices. It also directs FDA to publish a draft report and plan no later than 1 year after enactment of the Consolidated Appropriations Act and to consult with stakeholders in developing the report and implementation plan.

DATES: Submit either electronic or written comments on the draft report and plan by March 4, 2024.

ADDRESSES: You may submit comments 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–2023–N–5653 for ''Draft Report and Plan on Best Practices for Guidance.'' 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 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.

See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft report and plan.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993–0002, 301–827–4830.

SUPPLEMENTARY INFORMATION:

I. Background

Clear, concise, and timely communication through guidance documents is essential to the public health mission of FDA. FDA guidance documents are prepared for regulated industry, FDA staff, and the public to describe the Agency's interpretation of, or policy on, a regulatory issue. (§ 10.115(b) (21 CFR 10.115(b))). Unlike statutes and regulations, guidance documents generally do not establish legally enforceable rights or responsibilities (§ 10.115(d)), and are thus exempt from notice and comment requirements applicable to most rulemaking under the Administrative Procedure Act. (5 U.S.C. 553(b)(A); (d)(2)). However, the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA's Good Guidance Practices (GGP) regulation (§ 10.115) require FDA to provide an opportunity for public comment prior to implementation for all Level 1 guidance documents (*i.e.,* guidance documents that include initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues), unless FDA determines that prior public participation is not feasible or appropriate. (21 U.S.C.371(h)(1)(C)(i); 10.115(g)). If FDA decides that public participation is not feasible or appropriate prior to implementation of a guidance document, FDA must provide for public comment upon publication and take such comment into consideration. (21 U.S.C. 371(h)(1)(C)(i); 10.115(g)(3)). For Level 2 guidance documents (*i.e.,* guidance documents that set forth existing practices or minor changes in policy), the FD&C Act and FDA's GGP regulation require that FDA provide for public comment upon implementation. (21 U.S.C. 371(h)(1)(D); 10.115(g)(4)).

As part of FDA's Transparency Initiative, in 2011, FDA publicly released a comprehensive report entitled ''Food and Drug Administration Report on Good Guidance Practices: Improving Efficiency and Transparency'' (2011 GGP Report, available at *https://www.fda.gov/about-fda/transparency/transparency-initiative*). The 2011 GGP Report identified ''best practices'' and made recommendations to streamline the development of guidance documents, reduce the time between issuing draft and final guidance documents, and improve access to guidance documents on FDA's website. Since 2011, FDA has continued to make significant strides to modernize and improve our best practices for the efficient prioritization, development, review, clearance, and issuance of our guidance documents.

The Coronavirus Disease 2019 (COVID–19) Public Health Emergency (PHE) pushed us to consider innovative approaches to streamline guidance issuance and regulatory submissions to reach a broad audience in an expedited manner. The facts and circumstances surrounding COVID–19 and the COVID–19 PHE enabled FDA to rapidly disseminate Agency recommendations and policies related to COVID–19 to industry and other interested parties, FDA staff, and the public, including patients and consumers. The Agency used Paperwork Reduction Act waivers, issuance of Level 1 guidance documents without prior public participation, and expedited external review of guidance documents, which translated into significant time savings. These tools were critical to the significant work FDA accomplished during the COVID–19 pandemic. Now that the PHE determined under section 319 of the Public Health Service Act is over, FDA is considering the lessons learned from that experience and reassessing our current best practices for guidance to look for additional areas for improvement consistent with our statutory and regulatory framework.

In accordance with section 2505(a) of the Consolidated Appropriations Act of 2023 (Pub. L. 117–328), FDA's ''Draft Report and Plan on Best Practices for Guidance'' identifies our current best practices for the efficient prioritization, development, issuance, and use of guidance documents. As a part of this draft report and plan, FDA is also considering opportunities to streamline processes for regulatory submissions through the revision and issuance of guidance documents and to implement innovative guidance development processes and practices. Pursuant to section 2505(c) of the Consolidated Appropriations Act, in this **Federal Register** notice announcing the availability of this document, FDA is seeking public comment on this ''Draft Report and Plan on Best Practices for Guidance.''

II. Request for Comments

FDA is soliciting comments on its ''Draft Report and Plan on Best Practices for Guidance'' from a broad range of commenters, including regulated industry; researchers; academic organizations; pharmaceutical, biotechnology, and medical device developers; clinical research organizations; clinical laboratories; healthcare providers; food manufacturers; and consumer and patient groups. We are particularly interested in feedback on the following areas:

1. FDA regularly considers its processes for the development, clearance, and issuance of guidance documents, with a goal of streamlining these processes and making the best use of Agency resources. The draft report summarizes FDA's current best practices for the initiation, prioritization, development, review, clearance, and issuance of guidance documents that FDA has implemented in response to the 2011 report and other continual improvement efforts not described in the 2011 report. The draft report also proposes additional initiatives that FDA could consider to further improve its processes for the issuance of guidance documents. FDA solicits input on whether there are additional or revised practices, consistent with our statutory and regulatory framework, for the Agency to consider.

2. Level 1 guidance documents are guidance documents that include initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues. Level 2 guidance documents describe existing practices or minor changes in interpretation or policy. Pursuant to FDA's statutory and regulatory requirements, while the public may comment on a guidance document at any time, public participation is directly solicited prior to the implementation of Level 1 guidance documents unless we determine that such prior public participation is not feasible or appropriate. In the preamble to the final GGP rule, we noted that we anticipated that this exception would generally be applicable when there are public health reasons for the immediate implementation of the guidance document; there is a statutory requirement, executive order, or court order that requires immediate implementation; or the guidance document presents a less burdensome policy that is consistent with public health.[1] Issuing more guidance documents either as Level 1 guidance documents for immediate implementation, as FDA did during the COVID–19 PHE, or as Level 2 guidance documents would allow FDA to allocate its limited resources more efficiently, which would help FDA keep pace with rapid scientific developments and better serve the public health. In addition,

[1] 65 FR 56468 at 56472 (September 19, 2000).

FDA's GGP regulation provides that the public may comment on any guidance at any time, including Level 1 guidance documents for immediate implementation and Level 2 guidance documents, and FDA may delay implementation of any guidance document.

a. In light of the above, we seek input on whether there are any additional circumstances, categories of guidance documents, or topics for guidance for which it may be appropriate and consistent with the FD&C Act and FDA's GGP regulation for FDA to consider issuance as a Level 1 guidance document for immediate implementation without prior public comment.

b. We also seek comment on whether there are additional categories or types of guidance documents that FDA should consider issuing as Level 2 guidance documents to streamline the guidance process and allow the Agency to better leverage its resources for the timely development of more guidance documents.

3. FDA requests comment on any novel guidance document formats that would be of particular utility, such as use of templates to accompany a guidance document, Q&A formats, flowcharts, etc., that are used in FDA guidance documents or that were used in guidance documents issued in response to the COVID–19 PHE.

4. FDA makes robust use of guidance documents to assist industry in making regulatory submissions. As described in the report, examples of such guidances include device-specific guidance documents, disease or indication specific guidance documents that include recommendations on developing drugs intended to treat a specific disease or for a specific indication to support submissions of New Drug Applications (NDAs) or Supplemental NDAs, product specific guidances for generic drug development to support submission of Abbreviated New Drug Applications (ANDAs), Data Technical Conformance Guides to accompany guidance documents, and guidance documents that provide assistance with registration and listing requirements. FDA requests comment on the utility of guidances in streamlining regulatory submissions and whether there are additional categories or types of guidance that would be helpful to streamline processes for regulatory submissions to the Agency.

5. Currently, FDA's GGP regulation (§ 10.115) provides that interested persons can suggest areas for guidance document development and that such suggestions should address why a guidance document is necessary. (§ 10.115(f)(2)). In addition, proposed guidance documents can be submitted to a specified docket for FDA consideration. (§ 10.115(f)(3)). FDA requests comments on whether the currently available mechanisms for submitting suggested areas for guidance development and proposed guidance documents are useful and sufficient or whether additional mechanisms, for example, a Center-specific or Office-specific mailbox for such suggestions would ease the process for such submissions.

6. FDA Centers publish guidance agendas on their web pages to give interested parties and the public notice of the areas in which FDA is considering upcoming guidance. We request comment on the utility of these guidance agendas and what, if any, modifications to these agendas would be helpful for the Agency to consider.

III. Electronic Access

Persons with access to the internet may obtain the draft report and plan at *https://www.fda.gov/about-fda/reports/reports-agency-policies-and-initiatives* or *https://www.regulations.gov.*

Dated: December 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28872 Filed 1–2–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

FOR FURTHER INFORMATION CONTACT: Anastasia Flanagan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Flanagan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: In accordance with section 9.19 of the Mandatory Guidelines, a notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list.*

The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for Federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three