Annual Hours: 46,575. (For policy questions regarding this collection contact William Long at 410–786–7927.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Application and Triennial Re-application to Be a Qualified Entity to Receive Medicare Data for Performance Measurement; *Use:* The Patient Protection and Affordable Care Act (ACA) was enacted on March 23, 2010 (Pub. L. 111–148). ACA amends section 1874 of the Social Security Act by adding a new subsection (e) to make standardized extracts of Medicare claims data under Parts A, B, and D available to qualified entities to evaluate the performance of providers of services and suppliers. This is the application needed to determine an organization's eligibility as a qualified entity. The information from the collection is used by CMS to determine whether an organization meets the criteria required to be considered a qualified entity to receive Medicare claims data under ACA Section 10332. CMS evaluates the organization's eligibility in terms of organizational and governance capabilities, addition of claims data from other sources, and data privacy and security. This collection covers the application through which organizations provide information to CMS to determine whether they will be approved as a qualified entity. This collection also covers the triennial re-application (CMS–10596; 0938–1317) through which organizations provide information to CMS to determine whether they are approved to continue as a qualified entity. *Form Number:* CMS–10394 (OMB control number: 0938–1144); *Frequency:* Occasionally; *Affected Public:* Not-for-profits institutions and Business or other for-profits; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 3,800. (For policy questions regarding this collection contact Kari A. Gaare at 410–786–8612.)

Dated: January 18, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–01183 Filed 1–20–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0593]

Collecting and Providing 702(b) Portions of Food and Drug Administration Official Samples—Questions and Answers; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Collecting and Providing 702(b) Portions of FDA Official Samples—Questions and Answers.'' This draft guidance is intended to assist industry and FDA staff with issues and questions related to the requirements for FDA to collect and provide a part of an official sample of an article to any person named on the label of the article, or the owner thereof, or his attorney or agent.

DATES: Submit either electronic or written comments on the draft guidance by February 22, 2022 to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2021–D–0593 for ''Collecting and Providing 702(b) Portions and of FDA Official Samples—Questions and Answers.'' 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.'' We will review this copy, including the claimed confidential information, in our 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 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Chris Henderson, Office of Regulatory Affairs, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20857 240–402–8186, *Christopher.henderson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Collecting and Providing 702(b) Portions of FDA Official Samples—Questions and Answers.'' Section 702 of the FD&C Act (21 U.S.C. 372) authorizes FDA to conduct examinations and investigations and to collect samples. Under section 702(b) of the FD&C Act, when FDA collects a sample of a food, drug, or cosmetic for analysis, FDA must, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent. Additionally, FDA was authorized to establish, by regulation, reasonable exceptions to, and impose reasonable terms and conditions relating to, the requirement to collect and provide a 702(b) portion of an official sample to the owner, as necessary for the proper administration of the provisions of the FD&C Act. FDA's regulation at 21 CFR 2.10 was issued to establish those reasonable exceptions, and terms and conditions, and to implement section 702(b) of the FD&C Act.

This draft guidance is intended to assist industry and FDA staff with issues and questions related to the requirements for FDA to collect and provide portions of official samples under section 702(b) of the FD&C Act and its implementing regulation in 21 CFR 2.10.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Collecting and Providing 702(b) Portions of FDA Official Samples—Questions and Answers.'' 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

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/search-general-and-cross-cutting-topics-guidance-documents, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: January 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–01143 Filed 1–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1137, FDA–2020–D–1138, FDA–2020–D–0987]

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 January 21, 2022.

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