if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 511(e)(8)(A) of Title V of the Social Security Act requires that grantees under the Tribal MIECHV program, in the first year of their grants, submit an implementation plan on how they will meet the requirements of the program. Section 511(h)(2)(A) further states that the requirements for the MIECHV grants to tribes, tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for states and jurisdictions.

The ACF Office of Early Childhood Development, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau awarded grants for the Tribal MIECHV Program to support cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally relevant, evidence-based home visiting programs in at-risk tribal communities; establish, measure, and report on progress toward meeting performance measures in six legislatively mandated benchmark areas; and conduct rigorous evaluation activities to build the knowledge base on home visiting among Native populations.

During the first grant year, Tribal Home Visiting DIG and IEG grantees must comply with the requirement to submit an implementation plan that should feature planned activities to be carried out under the program in years 2–5 of their cooperative agreements. To assist grantees with meeting these requirements, ACF created guidance for grantees to use when writing their plans. The DIG and IEG guidance specify that grantees must provide a plan to address the following areas:

- Community Needs and Readiness Assessment
- Program Design
- Program Blueprint
- Plan for Data Collection, Management and Performance Measurement
- Fidelity Monitoring and Quality Assurance

Respondents: Tribal Home Visiting Managers (information collection does not include direct interaction with individuals or families that receive the services).

TOTAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Implementation Plan Guidance for Development and Implementation Grantees	13	1	1000	13,000
Implementation Plan Guidance for Implementation and Expansion Grantees	35	1	1000	35,000
Estimated Total Annual Burden Hours:				48,000

Authority: Title V of the Social Security Act, Sections 511(e)(8)(A) and 511(h)(2)(A).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–07845 Filed 4–12–23; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1188]

Over-the-Counter Monograph Order Requests: Format and Content; Draft 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 draft guidance for industry entitled ''Over-the-Counter Monograph Order Requests (OMORs): Format and Content.'' This draft guidance provides recommendations on the format and content of the information that a requestor should provide in an over-the-counter (OTC) monograph order request (OMOR) and identifies relevant guidance documents to assist requestors in preparing their OMORs.

DATES: Submit either electronic or written comments on the draft guidance by June 12, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins 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–2023–D–1188 for ''Over-the-Counter Monograph Order Requests (OMORs): Format and Content.'' 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.

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 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. 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: Trang Tran, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–7945.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Over-the-Counter Monograph Order Requests (OMORs): Format and Content.'' This draft guidance is intended to assist requestors in preparing OMORs for submission to FDA under section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h). This draft guidance provides recommendations on the format and content of the information that a requestor should provide in an OMOR and identifies relevant guidance documents to assist requestors in preparing their OMORs.

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136), which was enacted on March 27, 2020. As required by section 505G(l) of the FD&C Act, this draft guidance, when finalized, will discuss the format and content of data submissions, specifically OMORs, to FDA.

In support of the CARES Act, FDA agreed to specific performance goals and procedures described in the document ''Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022,'' commonly referred to as the OMUFA Commitment Letter (the document can be accessed at *https://www.fda.gov/media/106407/download* and the document with updated goal dates for fiscal years 2021–2025 can be accessed at *https://www.fda.gov/media/146283/download*). In the OMUFA Commitment Letter, FDA committed to issuing this draft guidance under specific timelines.

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 ''Over-the-Counter Monograph Order Requests (OMORs): Format and Content.'' 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

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 (chapter 35 of title 44, United States Code) does not apply to collections of information made under section 505G of the FD&C Act. The information collections described in this guidance implement the following provisions of section 505G:

(1) Section 505G(b)(5) of the FD&C Act, which allows submission of administrative orders, OMORs, initiated at the request of a requestor.

(2) Section 505G(b)(6) of the FD&C Act, which allows requestors to provide certain information regarding safe nonprescription product marketing and use as a condition for filing a generally recognized as safe and effective request.

(3) Section 505G(d) of the FD&C Act confidentiality of information submitted to the Secretary, which requires FDA to make information submitted in support of an OMORs available to the public no later than the date of the proposed order unless it meets certain limitations on public availability.

(4) Section 505G(j) of the FD&C Act, which requires that all submissions under section 505G must be in electronic format.

(5) Section 505G(l)(1) of the FD&C Act, which requires FDA to issue guidance that specifies the procedures and principles for formal meetings between the Secretary and sponsors or requestors for drugs subject to section 505G.

(6) Section 505G(1)(2) of the FD&C Act, which requires FDA to issue guidance that specifies the format and content of data submissions to the Secretary under section 505G.

(7) Section 505G(1)(3) of the FD&C Act, which requires FDA to issue guidance that specifies the format of electronic submissions to the Secretary under section 505G.

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 collections of information. In addition, this guidance refers to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the PRA. The collections of

information for OTC monograph products, OTC monograph order requests, and the OTC Monograph User Fee Program have been approved under OMB control number 0910–0340. The information collections for submission of new drug applications and abbreviated new drug applications in 21 CFR part 314 are approved under OMB control number 0910–0001. The collections of information used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses under 21 CFR part 25 have been approved under OMB control number 0910–0322.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07767 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1052]

Food and Drug Administration Data and Technology Strategic Plan; Request for Information and Comments

AGENCY: Food and Drug Administration, Department of Health and Human Services.

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a request for information and comments on the development of an FDA Data and Technology Strategic Plan. As part of our User Fee Program commitments and Omnibus Bill requirements, FDA will develop and publish an FDA Data and Technology Strategic Plan by September 30, 2023. This plan will define and shape the future course of FDA's data and technology capabilities, building on the existing FDA Modernization Framework. The plan will also integrate Agency and center strategies.

DATES: Submit either electronic or written comments on the request for information and comments by May 15, 2023 to ensure that the Agency considers your comments before it begins work on the final version of the strategy.

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–1052 for ''FDA Data and Technology Strategic Plan.'' 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.

FOR FURTHER INFORMATION CONTACT: Casi Alexander, Office of Digital Transformation, Food and Drug Administration, FDA Library, 5630 Fishers Lane, Rm. 1087, Rockville, MD 20857, 240–402–5171, email: *Casi.Alexander@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a request for information and comments entitled ''FDA Data and Technology Strategic Plan; Request for Information and Comments.''

The Office of Digital Transformation (ODT) was established in September 2021 and reports directly to the Office of the Commissioner. ODT provides the vision and leadership in information technology, data, and cybersecurity needed to advance FDA's mission and strategic priorities. ODT has published a series of strategy documents known as