an article that appears violative, we provide notice to the owner or consignee of the nature of the violation and the right to present testimony regarding the admissibility of the article (21 CFR 1.94). Frequently, owners or consignees submit analytical test results based on samples taken from the article subject to DWPE as evidence demonstrating admissibility. We then determine if the testimony (analytical package, information, or other evidence) is sufficient. If the evidence is adequate to overcome the appearance of the violation(s), FDA will allow the article to proceed for entry into the United States. If the evidence is not adequate to remove the appearance of the violation(s), the entry will be refused admission into the United States.

In addition, interested parties may request that their products be removed from DWPE. FDA decisions to remove a product, manufacturer, or other entity from DWPE are based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and we have confidence that future shipments of the product to the United States will be in compliance with the FD&C Act. FDA may consider analytical results from successful consecutive tests as part of the evidence to support removal from DWPE.

The draft guidance, when finalized, will provide recommendations for collecting a representative sample for products subject to DWPE under an import alert due to the appearance of adulteration caused by pathogens, unlawful animal drugs, scombrotoxin (histamine), and/or decomposition. When finalized, the draft guidance will also help foreign manufacturers and other processors of fish and fishery products subject to DWPE introduce evidence to FDA to support a request to have products removed from DWPE.

The recommendations in the draft guidance include sample sizes based on a critical nonconformities sampling strategy. Using this statistical sampling equation, the amount of sampling recommended can be structured commensurate with the level of concern, and risk to consumers, associated with the type of adulteration to be addressed. For more information, see ''Derivation of Sampling Recommendations Related to Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer's Goods from DWPE; Guidance for Industry'' (Ref. 1). As the draft guidance makes clear, persons may propose alternative sampling plans and explain the basis for such alternatives.

We note that the draft guidance refers to the final rule entitled ''Laboratory Accreditation for Analyses of Foods'' (LAAF Rule, which is codified at 21 CFR part 1, subpart R). FDA is taking a stepwise approach to implementing the LAAF Rule based, in part, on reaching sufficient LAAF-accredited laboratory capacity for food testing (see 86 FR 68728 at 68739 and 68740, December 3, 2021). FDA may publish one or more documents in the **Federal Register** giving owners and consignees 6 months' notice before requiring them to use a LAAF-accredited laboratory for food testing covered by the rule (id.). We will monitor LAAF Rule implementation and update any final guidance based on this draft guidance accordingly.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 1, subpart R have been approved under OMB control number 0910–0898.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/FoodGuidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

IV. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov*.

1. FDA, ''Derivation of Sampling Recommendations Related to Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer's Goods from DWPE; Guidance for Industry.''

Dated: February 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02838 Filed 2–9–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4974]

Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability entitled ''Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request'' that appeared in the **Federal Register** of December 13, 2023. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published on December 13, 2023 (88 FR 86333). Either electronic or written comments must be submitted by March 13, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 13, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–4974 for ''Advanced Manufacturing Technologies Designation Program.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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:

With regard to the draft guidance: Ranjani Prabhakara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6648, Silver Spring, MD 20993, 240–402–4652; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 13, 2023, FDA published a notice of availability with a 60-day comment period to provide comments on the draft guidance entitled ''Advanced Manufacturing Technologies Designation Program'' and its proposed collection of information. FDA has received requests to extend the comment period to allow sufficient time to develop and submit meaningful comments. FDA has considered the requests and is extending the comment period for 30 days, until March 13, 2024. The Agency believes that this extension allows adequate time for interested persons to submit comments.

II. Electronic Access

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

Dated: February 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02836 Filed 2–9–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0119]

Fiscal Year 2024 Generic Drug Science and Research Initiatives Workshop; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''FY 2024 Generic Drug Science and Research Initiatives Workshop.'' The purpose of the public workshop is to provide an overview of the status of science and research initiatives for generic drugs and an opportunity for public input on these initiatives. FDA is seeking this input from a variety of stakeholders—