Submissions for Management of Cybersecurity in Medical Devices,'' issued October 2, 2014. The changes since the 2014 guidance are intended to further emphasize the importance of ensuring that devices are designed securely and are designed to be capable of mitigating emerging cybersecurity risks throughout the total product lifecycle (TPLC), and to clearly outline FDA's recommendations for premarket submission information to address cybersecurity concerns. As discussed in the guidance, one way these TPLC considerations for devices can be achieved is through the implementation and adoption of the Secure Product Development Framework. The recommendations in this guidance are intended to promote consistency, facilitate efficient premarket review, and help ensure that marketed medical devices are sufficiently resilient to cybersecurity threats.

A notice of availability of the draft guidance appeared in the **Federal Register** of April 8, 2022 (87 FR 20873). FDA considered comments received and revised the guidance as appropriate in response to the comments, including aligning with industry best practices, as well as further clarifying the level of documentation recommended. Additionally, we have clarified interoperability considerations and that cybersecurity controls should not be intended to prohibit a user from accessing their device data.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.'' 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. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/ device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https:// www.fda.gov/regulatory-information/ search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions'' may send an email request to *CDRH-Guidance@ fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00001825 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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 under the Paperwork Reduction Act of 1995. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Use Devices; Humanitarian Device Exemption ...	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-Submissions and early payor feedback request programs for medical devices.	0910–0756
800, 801, 809, and 830	Medical device labeling regulations; Unique device identification.	0910–0485
820	Current good manufacturing practice (CGMP); Quality system (QS) regulation.	0910–0073

Dated: September 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20955 Filed 9–26–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0487]

Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice, published in the **Federal Register** of March 1, 2023, establishing a public docket and requesting information and comments. FDA is reopening the comment period to update comments and to receive any new information.

DATES: FDA is reopening the comment period on the notice published March 1, 2023 (88 FR 12943). Either electronic or written comments must be submitted by November 27, 2023.

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 November 27, 2023. 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–N–0487 for "Discussion Paper: Artificial Intelligence in Drug Manufacturing, Notice; Request for Information and Comments." 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.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4162, Silver Spring, MD 20993, 240–402–7930, *Elizabeth.Giaquinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 1, 2023 (88 FR 12943), FDA established a public docket to solicit comments on the "Discussion Paper: Artificial Intelligence in Drug Manufacturing." The discussion paper presents areas for consideration and policy development identified by the Center for Drug Evaluation and Research (CDER) scientific and policy experts associated with application of artificial intelligence to pharmaceutical manufacturing. The discussion paper includes a series of questions to stimulate feedback from the public, including CDER and the Center for Biologics Evaluation and Research stakeholders.

Interested persons were originally given until May 1, 2023, to comment on the content of the discussion paper.

Following publication of the March 1, 2023, notice, FDA has decided to reopen the public docket to allow interested persons additional time to comment on the discussion paper. We note that there is also a public workshop organized by FDA and the Product Quality Research

Institute entitled "Regulatory Framework for the Utilization of Artificial Intelligence in Pharmaceutical Manufacturing: An Opportunity for Stakeholder Engagement," which is scheduled for September 26 and 27, 2023 (*https://pqri.org/fda-pqri-aiworkshop/*).

Dated: September 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20902 Filed 9–26–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0324]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before November 27, 2023.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0324–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@ HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Report of Dental Examination of Applicants to the Public Health Service Commissioned Corps.