SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of two draft chapters entitled ''Chapter 11—Food Allergen Program'' and ''Chapter 16—Acidified Foods'' of a multichapter draft guidance for industry entitled ''Hazard Analysis and Risk-Based Preventive Controls for Human Food.'' We previously announced the availability of several chapters of that draft guidance as shown in table 1.

TABLE 1—AVAILABLE DRAFT CHAPTERS IN HAZARD ANALYSIS AND RISK-BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

Chapter No.	Chapter title	Publication
N/A	Introduction	81 FR 57816, August 24, 2016.
1	The Food Safety Plan	81 FR 57816, August 24, 2016.
2	Conducting a Hazard Analysis	81 FR 57816, August 24, 2016.
3	Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food.	81 FR 57816, August 24, 2016.
4	Preventive Controls	81 FR 57816, August 24, 2016.
5	Application of Preventive Controls and Preventive Control Management Components	81 FR 57816, August 24, 2016.
6	Use of Heat Treatments as a Process Control	82 FR 41364, August 31, 2017.
14	Recall plan	84 FR 53347, October 7, 2019.
15	Supply-Chain Program for Human Food Products	83 FR 3449, January 25, 2018.
Appendix 1	Potential Hazards for Foods and Processes	81 FR 57816, August 24, 2016.
Appendix 2	Food Safety Plan Forms	81 FR 57816, August 24, 2016.
Appendix 3	Bacterial Pathogen Growth and Inactivation	81 FR 57816, August 24, 2016.

We also are announcing changes to the expected table of contents for the complete multichapter guidance.

We are issuing these chapters of the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on how to comply with the requirements for hazard analysis and risk-based preventive controls under part 117 (21 CFR part 117), principally in subparts C and G. 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.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production.

Section 103 of FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 418 (21 U.S.C. 350g) with requirements for hazard analysis and risk-based preventive controls for establishments that are required to register as food facilities under our regulations in 21 CFR part 1, subpart H, in accordance with section 415 of the FD&C Act (21 U.S.C. 350d). We have established regulations to implement these requirements within part 117.

We intend to announce the availability for public comment of additional chapters of the draft guidance as we complete them. The titles of the additional chapters that we expect to make available for public comment are included in the table of contents for the complete multichapter guidance.

III. 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 part 117 have been approved under OMB control number 0910–0751.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/FoodGuidances, *https://www.fda.govregulatory-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.

Dated: September 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20738 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–2021–D–1158]

Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions; 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 Agency) is announcing the availability of a final guidance entitled ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.'' As more medical devices are becoming interconnected, cybersecurity threats have become more numerous, more frequent, more severe, and more clinically impactful. As a result, ensuring medical device safety and effectiveness includes adequate medical device cybersecurity, as well as its security as part of the larger system. This final guidance supersedes the final guidance ''Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,'' issued October 2, 2014.

DATES: The announcement of the guidance is published in the **Federal Register** on September 27, 2023.

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 Docket No. FDA–2021–D–1158 for ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Suzanne Schwartz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5410, Silver Spring, MD 20993–0002, 301–796–6937; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

With the increasing integration of wireless, internet- and network-connected capabilities, portable media (*e.g.,* USB or CD), and the frequent electronic exchange of medical device-related health information and other information, the need for robust cybersecurity controls to ensure medical device safety and effectiveness has become more important. In addition, cybersecurity threats to the healthcare sector have become more frequent and more severe, carrying increased potential for clinical impact. Cybersecurity incidents have rendered medical devices and hospital networks inoperable, disrupting the delivery of patient care across healthcare facilities in the United States and globally. Such cyberattacks and exploits may lead to patient harm as a result of clinical hazards, such as delay in diagnoses and/or treatment. As a result, ensuring device safety and effectiveness includes adequate device cybersecurity, as well as its security as part of the larger system.

Additionally, section 3305 of the Consolidated Appropriations Act, 2023, enacted on December 29, 2022, added section 524B ''Ensuring Cybersecurity of Medical Devices'' to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under section 524B(a) of the FD&C Act, a person who submits a 510(k), premarket approval application (PMA), product development protocol, De Novo, or Humanitarian Device Exemption for a device that meets the definition of a cyber device, as defined under section 524B(c) of the FD&C Act, is required to submit information to ensure that cyber devices meet the cybersecurity requirements under section 524B(b) of the FD&C Act. Section 524B(c) of the FD&C Act defines ''cyber device'' as a device that includes software validated, installed, or authorized by the sponsor as a device or in a device; has the ability to connect to the internet; and contains any such technological characteristics validated, installed, or authorized by the sponsor that could be vulnerable to cybersecurity threats. The recommendations in this guidance are intended to help manufacturers meet their obligations under section 524B of the FD&C Act.

This final guidance supersedes the final guidance ''Content of Premarket

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,