4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-1030]

Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems under section 524B of the FD&C Act; 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, Agency, or we) is announcing the availability of a final guidance entitled "Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under section 524B of the FD&C Act of the FD&C Act." FDA generally intends not to issue "refuse to accept" (RTA) decisions for premarket submissions submitted for cyber devices based solely on information required by the new amendments to the FD&C Act for ensuring cybersecurity of devices before October 1, 2023, but instead, work collaboratively with sponsors of such premarket submissions as part of the interactive and/or deficiency review process.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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-2023-D-1030 for "Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act." 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 Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act" 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 Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-8113.

SUPPLEMENTARY INFORMATION:

I. Background

On December 29, 2022, the Consolidated Appropriations Act, 2023 ("Omnibus") was signed into law. Section 3305 of the Omnibus--"Ensuring Cybersecurity of Medical Devices"--amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 524B, Ensuring Cybersecurity of Devices. The Omnibus states that the amendments to the FD&C Act shall take effect 90 days after the enactment of the Consolidated Appropriations Act on March 29, 2023. As provided by the Omnibus, the cybersecurity requirements do not apply to an application or submission submitted to FDA before March 29, 2023.

FDA generally intends not to issue RTA decisions for premarket submissions submitted for cyber devices based solely on information required by section 524B of the FD&C Act before October 1, 2023, but instead, work collaboratively with sponsors of such premarket submissions as part of the interactive and/or deficiency review process. Beginning October 1, 2023, FDA expects that such sponsors will have had sufficient time to prepare premarket submissions that contain information required by section 524B of the FD&C Act, and FDA may RTA premarket submissions that do not.

We are implementing this guidance without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and

§ 10.115 (21 CFR 10.115(g)(2))). We made this determination because it is not feasible to obtain public comment prior to the 90-day statutory timeframe for the effective date of section 524B of the FD&C Act. This provision establishes new cybersecurity requirements for cyber devices, which includes information that a sponsor of a premarket submission for a cyber device must provide in its submission. This guidance communicates the Agency's policy regarding RTA decisions for premarket submissions submitted for such cyber devices, which is important to communicate before the effective date of the statutory provision, which is March 29, 2023. Although this policy is being implemented immediately without prior comment, FDA will consider all comments received and revise the guidance document as appropriate.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on "Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act." 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: Premarket Submission Considerations for Cyber Devices and Related Systems Under Section 524B of the FD&C Act" may send an email request to CDRH-

Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00007021 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. 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 this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance 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 Device Exemption	0910-0332
860, subpart D	De Novo classification process	0910-0844
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"	Q-submissions	0910-0756

Dated: March 27, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-06646 Filed: 3/29/2023 8:45 am; Publication Date: 3/30/2023]