

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by May 1, 2023.

**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](http://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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786–4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* The Home Health Care CAHPS® Survey (HHCAPHS); *Use:* The national implementation of the Home Health Care CAHPS Survey is designed to collect ongoing data from samples of home health care patients who receive skilled services from Medicare-certified home health agencies. The survey is necessary because it fulfills the goal of transparency with the public about home health patient experiences.

The survey is used by Medicare-certified home health agencies to

improve their internal quality assurance in the care that they provide in home health. The HHCAPHS survey is also used in a Medicare payment program. Medicare-certified home health agencies (HHAs) must contract with CMS-approved survey vendors that conduct the HHCAPHS on behalf of the HHAs to meet their requirements in the Home Health Quality Reporting Program *Form Number:* CMS–10275 (OMB control number: 0938–1066); *Frequency:* Quarterly; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,052,966; *Total Annual Responses:* 1,149,975; *Total Annual Hours:* 420,576. (For policy questions regarding this collection contact Lori Luria at 410–786–6684).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Collection of Diagnostic Data in the Abbreviated RAPS Format from Medicare Advantage Organizations for Risk Adjusted Payments; *Use:* Under section 1894(d) of the Act, CMS must make prospective monthly capitated payments to PACE organizations in the same manner and from the same sources as payments to organizations under section 1853. Section 1894(e)(3)(A)(i) requires in part that PACE organizations collect data and make available to the Secretary reports necessary to monitor the cost, operation, and effectiveness of the PACE program.

CMS makes advance monthly per-enrollee payments to organizations, and is required to risk-adjust the payments based on predicted relative health care costs for each enrollee, as determined by enrollee-specific diagnoses and other factors, such as age. CMS has collected diagnosis data from organizations in two formats: (1) comprehensive data equivalent to Medicare fee-for-service claims data (often referred to as encounter data) and (2) data in an abbreviated format known as RAPS data, named for the Risk Adjustment Processing System (RAPS). The subject of this PRA package is collection of RAPS data. Encounter data collection is addressed in a separate PRA package (OMB 0938–1152).

Risk adjustment allows CMS to pay plans for the health risk of the beneficiaries they enroll, instead of paying an identical an average amount for each enrollee Medicare beneficiaries. By risk adjusting plan payments, CMS is able to make appropriate and accurate payments for enrollees with differences in expected costs. Risk adjustment is used to adjust bidding and payment based on the health status and demographic characteristics of an

enrollee. Risk scores measure individual beneficiaries’ relative risk and the risk scores are used to adjust payments for each beneficiary’s expected expenditures. By risk adjusting plan bids, CMS is able to also use standardized bids as base payments to plans. *Form Number:* CMS–10062 (OMB control number: 0938–0878); *Frequency:* Quarterly; *Affected Public:* Private Sector, Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 284; *Total Annual Responses:* 80,235,720; *Total Annual Hours:* 2,674,524. (For policy questions regarding this collection contact Amanda Johnson at 410–786–4161.

Dated: March 24, 2023.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2023–06564 Filed 3–29–23; 8:45 am]

**BILLING CODE 4120–01–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 March 30, 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-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](mailto: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 3–29–23; 8:45 am]  
**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2020–N–0026]

**Issuance of Priority Review Voucher; Rare Pediatric Disease Product**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the

award of the priority review voucher. FDA has determined that DAYBUE (trofinetide), approved March 10, 2023, and manufactured by Acadia Pharmaceuticals, Inc., meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:** Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: [Cathryn.Lee@fda.hhs.gov](mailto:Cathryn.Lee@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that DAYBUE (trofinetide), manufactured by Acadia Pharmaceuticals, Inc., meets the criteria for a priority review voucher. DAYBUE (trofinetide) solution is for the treatment of Rett Syndrome in adults and pediatric patients 2 years of age and older.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about DAYBUE (trofinetide), go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: March 27, 2023.  
**Lauren K. Roth,**  
*Associate Commissioner for Policy.*  
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**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2023–D–0266]

**Identification of Medicinal Products—Implementation and Use; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.