meeting to take place using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. No participant will be prejudiced by this waiver, and that the ends of justice will be served by allowing for this modification to FDA's advisory committee meeting procedures.

Dated: September 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19284 Filed 9–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2607]

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) 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 SOHONOS (palovarotene), manufactured by Ipsen Biopharmaceuticals, 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.*

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), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that SOHONOS (palovarotene), approved on August 16, 2023, and manufactured by Ipsen Biopharmaceuticals, Inc., meets the criteria for a priority review voucher. SOHONOS (palovarotene) capsules are indicated for reduction in volume of new heterotopic ossification in adults and pediatric patients (aged 8 years and older for females and 10 years and older for males) with fibrodysplasia ossificans progressiva.

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 *http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about SOHONOS (palovarotene), go to the ''Drugs@FDA'' website at *http://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: September 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19289 Filed 9–6–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–D–3132, FDA–2023–D–3133, and FDA–2023–D–3134]

Modernizing the Food and Drug Administration's Premarket Notification Program; Draft Guidances 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 three draft guidances entitled ''Evidentiary Expectations for 510(k) Implant Devices,'' ''Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions,'' and ''Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission.'' FDA is issuing these guidances to improve the predictability, consistency, and transparency of the 510(k) premarket review process. The draft guidances are not final nor are they for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 6, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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 Docket No. FDA–2023–D–3132 for ''Evidentiary Expectations for 510(k) Implant Devices,'' Docket No. FDA–2023–D–3133 for ''Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions,'' or Docket No. FDA–2023–D–3134 for ''Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission.'' 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 draft guidance document entitled ''Evidentiary Expectations for 510(k) Implant Devices,'' ''Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions,'' or ''Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission'' 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: Angela DeMarco, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2436, Silver Spring, MD 20993–0002, 301–796–4471; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7242, Silver Spring, MD 20993, 240–402–8113.

SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA's Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health,[1] FDA committed to strengthen and modernize the premarket notification (510(k)) Program. FDA is issuing these three draft guidances to enhance the transparency, consistency, and predictability of the 510(k) premarket review process.

In ''Evidentiary Expectations for 510(k) Implant Devices,'' FDA discusses considerations that are generally relevant to all types of implants subject to 510(k) requirements. This draft guidance is intended to serve as a primary resource, used in conjunction with other guidances, to provide clarity and facilitate discussions regarding expectations for performance data that may be necessary to establish substantial equivalence for implanted medical devices. However, the type and quantity of performance data needed to support a substantial equivalence determination for a particular device will vary depending on the device and/or device type and on the differences from the predicate device.

In ''Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions,'' FDA clarifies and provides additional context for situations when clinical data may be necessary to demonstrate substantial equivalence, as initially described in the final guidance ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'' [2] (''510(k) Program Guidance''). This draft guidance expands on the scenarios described in the 510(k) Program Guidance, describes another scenario, and provides additional examples to illustrate when clinical data may or may not be necessary to include in a 510(k) submission to demonstrate substantial equivalence.

Finally, in ''Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission,'' FDA proposes four best practices for choosing a predicate device used to support a 510(k) submission. Initially, FDA considered making public on its website those cleared devices that demonstrated substantial equivalence to older predicate devices. FDA also considered focusing on predicates that were more than 10 years old as a starting point. FDA issued a public notice on its website that requested public comment on this proposal.[3] After considering the docket comments, FDA believes use of best practices that encourage the use of predicate devices with certain characteristics, rather than focusing on the age of the predicate, will support modernization of the 510(k) Program with respect to the use of predicate devices and encourage the evolution of safer and more effective medical devices.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent the current thinking of FDA on the topics discussed in ''Evidentiary Expectations for 510(k) Implant Devices,'' ''Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions,'' and ''Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission.'' These draft guidances do not establish any rights for any person and are 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 copies of these draft guidances may do so by downloading electronic copies 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-*

[1] Available at *https://www.fda.gov/about-fda/cdrh-reports/medical-device-safety-action-plan-protecting-patients-promoting-public-health.*

[2] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.*

[3] Available at *https://wayback.archive-it.org/7993/20190206202131/https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm604500.htm.* Public comments submitted can be searched under the docket FDA–2018–N–4751, available at *https://www.regulations.gov/docket/FDA-2018-N-4751.*

regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. These guidance documents are 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 ''Evidentiary Expectations for 510(k) Implant Devices'' (document number GUI00020017), ''Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions'' (document number GUI00020016), or ''Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission'' (document number GUI00020006) may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidances contain no new collection of information, they do 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 the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
''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
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
810	Medical Device Recalls	0910–0432
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073
822	Postmarket Surveillance of Medical Devices	0910–0449
Forms FDA 3500 and FDA 3500A	Medical device adverse event reporting—MedWatch	0910–0291
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies	0910–0119

Dated: September 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19283 Filed 9–6–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Public Comment Request; Information Collection Request Title: Health Professions Student Loan Program, Loans for Disadvantaged Students Program, Primary Care Loan Program, and Nursing Student Loan Program Administrative Requirements, OMB No. 0915–0047—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for the opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate below; or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than November 6, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at 301–443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Health Professions Student Loan (HPSL) Program, Loans for Disadvantaged Students (LDS) Program, Primary Care Loan (PCL) Program, and Nursing Student (Loan (NSL) Program Administrative Requirements, OMB No. 0915–0047—Revision.

Abstract: This clearance request is for approval of the HPSL Program, LDS Program, PCL Program, and NSL Program Administrative Requirements.

The HPSL Program, authorized by Public Health Service (PHS) Act sections 721–722 and 725–735, is a grant program where recipients provide long-term, low-interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The LDS Program, authorized by PHS Act sections 721–722 and 724–735, is a grant program where recipients provide long-term, low interest loans to certain students attending schools of allopathic medicine, osteopathic medicine, podiatric medicine, dentistry, optometry, pharmacy, and veterinary medicine. The PCL Program, authorized by PHS Act sections 721–723 and 725–735, is a grant program where recipients provide long-term, low interest loans to students attending schools of allopathic medicine and osteopathic medicine to practice primary health care. The NSL Program, authorized by PHS Act sections 835–842, is a grant program where recipients provide long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma degree, an associate degree, a baccalaureate degree, or a graduate degree in nursing. These programs also have a number of recordkeeping and reporting requirements for academic institutions and loan applicants. The applicable program regulations are found in 42 CFR 57.201–218 and 57.301–318. HRSA proposes revisions to the Annual