

the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the 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 MEPSEVII (vestronidase alfa-vjbc), manufactured by Ultragenyx Pharmaceutical, Inc., meets the criteria for a priority review voucher.

**FOR FURTHER INFORMATION CONTACT:**

Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-4061, Fax: 301-796-9856, email: [althea.cuff@fda.hhs.gov](mailto:althea.cuff@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 MEPSEVII (vestronidase alfa-vjbc), manufactured by Ultragenyx Pharmaceutical, Inc., meets the criteria for a priority review voucher. MEPSEVII (vestronidase alfa-vjbc) is indicated for the treatment of Mucopolysaccharidosis type VII (MPS VII, Sly Syndrome).

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 MEPSEVII (vestronidase alfa-vjbc), go to the "Drugs@FDA" website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: December 12, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-D-6702]

**The Least Burdensome Provisions: Concept and Principles; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**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 the draft guidance entitled "The Least Burdensome Provisions: Concept and Principles" FDA utilizes a least burdensome approach to medical device regulation to eliminate unnecessary burdens that may delay the marketing of beneficial new products, while maintaining the statutory requirements for clearance and approval. This document describes the guiding principles and recommended approach for FDA staff and industry to facilitate consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by February 13, 2018 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 the Docket No. FDA-2017-D-6702 for "The Least Burdensome Provisions: Concept and Principles; Draft Guidance for Industry and Food and Drug Administration Staff; Availability." 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.

- *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.gpo.gov/fdsys/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.

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 “The Least Burdensome Provisions: Concept and Principles” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Joshua Silverstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–5155; and Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The FD&C Act, as amended by the FDA Modernization Act of 1997, the FDA Safety and Innovation Act (FDASIA), and the 21st Century Cures Act (Cures Act), includes least burdensome provisions that direct the Food and Drug Administration (FDA or Agency) to take a least burdensome approach to medical device evaluation in a manner that eliminates unnecessary burdens that may delay the marketing of beneficial new products, while maintaining the statutory requirements for clearance and approval. The updates to the least burdensome provisions in FDASIA and the Cures Act clarified the original least burdensome provisions and further recognized the role of postmarket activities as they relate to premarket decisions. FDA believes, as a matter of policy, that least burdensome principles should be consistently and widely applied to all activities in the premarket and postmarket settings to remove or reduce unnecessary burdens so that patients can have earlier and continued access to high quality, safe, and effective devices. This draft guidance, therefore, reflects FDA’s belief that least burdensome principles should be applied throughout the medical device total product lifecycle.

For the purposes of this guidance, FDA defines “least burdensome” as the minimum amount of information necessary to adequately address a regulatory question or issue through the most efficient manner at the right time. This draft guidance describes the least burdensome guiding principles and recommended approach for FDA staff and industry to ensure consistent application of least burdensome principles to the activities pertaining to products meeting the statutory definition of a device regulated under the FD&C Act. This guidance document, when finalized, will replace the 2002 Least Burdensome Guidance entitled “The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles” (October 4, 2002).

**II. Significance of Guidance**

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “The Least Burdensome Provisions: Concept and Principles.” 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. This guidance is not subject to Executive Order 12866.

**III. Electronic Access**

Persons interested in obtaining a copy of the draft 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <https://www.regulations.gov>. Persons unable to download an electronic copy of “The Least Burdensome Provisions: Concept and Principles; Draft Guidance for Industry and Food and Drug Administration Staff” 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 1332 to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). 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; guidance; or FDA form	Topic	OMB control No.
820 .....	Quality system regulation .....	0910–0073
812 .....	Investigational device exemption .....	0910–0078
807, subpart E .....	Premarket notification .....	0910–0120
860.123 .....	Reclassification petition .....	0910–0138
814, subparts A through E .....	Premarket approval .....	0910–0231
814, subpart H .....	Humanitarian device exemption .....	0910–0332
803 .....	Medical device reporting .....	0910–0437
822 .....	Postmarket surveillance .....	0910–0449
Form FDA 3670 .....	Adverse event reports/MedSun program .....	0910–0471

21 CFR part; guidance; or FDA form	Topic	OMB control No.
801 and 809 .....	Labeling .....	0910-0485
"Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices".	CLIA waiver .....	0910-0598
807, subparts A through D .....	Registration and listing .....	0910-0625
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff".	Q-submissions .....	0910-0756
"De Novo Classification Process (Evaluation of Automatic Class III Designation)".	De Novo classification process .....	0910-0844

Dated: December 11, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Rural Health Opioid Program Grant Performance Measures, OMB No. 0906-xxxx-New**

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

**ACTION:** Notice

**SUMMARY:** In compliance with the requirement for 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 February 13, 2018.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA

Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 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](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

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

*Information Collection Request Title:* Rural Health Opioid Program Grant Performance Measures.

OMB No. 0906-xxxx-New.

*Abstract:* The Rural Health Opioid Program aims to promote rural health care services outreach by expanding the delivery of opioid related health care services to rural communities. The program will work to reduce the morbidity and mortality related to opioid overdoses in rural communities through the development of broad community consortiums to prepare individuals with opioid-use disorder to start treatment, implement care coordination practices to organize patient care activities, and support individuals in recovery through the enhancement of behavioral counselling and peer support activities.

*Need and Proposed Use of the Information:* For this program, performance measures were drafted to provide data to the program and to

enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Target population demographics; (b) referrals to substance abuse treatment; (c) substance abuse treatment process and outcomes; (d) education of health care providers and community members; and (e) rates of fatal and non-fatal opioid-related overdose. All measures will speak to FORHP's progress toward meeting the goals set.

*Likely Respondents:* The respondents would be recipients of the Rural Health Opioid Program grant funding.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

*Total Estimated Annualized Burden Hours:*

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Rural Health Opioid Program Grant Performance Measures .....	10	1	10	11	110
.....	10	.....	10	.....	110

HRSA specifically requests comments on: (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