

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-10571]

Agency Information Collection Activities: Proposed Collection; Comment Request**AGENCY:** Centers for Medicare & Medicaid Services, HHS.**ACTION:** Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by February 13, 2018.**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the

proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.**SUPPLEMENTARY INFORMATION:****Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10571 Limited Wraparound Coverage Reporting

Under the 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 requires federal agencies to publish a 60-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.

Information Collection

1. *Type of Information Collection Request:* New collection of information request; *Title of Information Collection:* Limited Wraparound Coverage Reporting; *Use:* The Department of Treasury, the Department of Labor and the Department of Health and Human Services published final regulations on March 18, 2015 (80 FR 13995), amending the regulations regarding excepted benefits under the Employee Retirement Income Security Act of 1974, the Internal Revenue Code, and the Public Health Service Act to specify requirements for limited wraparound coverage to qualify as an excepted benefit. The final regulations include requirements that limited wraparound

coverage must satisfy in order to qualify as excepted benefits. One of them is a reporting requirement, for group health plans and group health insurance issuers, as well as group health plan sponsors.

A self-insured group health plan, or a health insurance issuer offering or proposing to offer Multi-State Plan wraparound coverage, is required to report to OPM information reasonably required to determine whether the plan or issuer qualifies to offer such coverage or complies with the applicable requirements. In addition, the plan sponsor of any group health plan offering any type of limited wraparound coverage is required to report to the Department of Health and Human Services (HHS), in a form and manner specified in guidance by the Secretary of HHS.

We seek comment on the content of the proposed collection form. We also seek comment on the impact that an extension of the limited wraparound pilot program would have on the number of employers/sponsors participating in the limited wraparound pilot program. In addition, if HHS extends the limited wraparound pilot program, we seek comment on when the limited wraparound pilot program should sunset, or whether the limited wraparound pilot program should be made permanent. *Form Number:* CMS-10571 (OMB control number: 0938-NEW); *Frequency:* Once; *Affected Public:* Private Sector; *Number of Respondents:* 8; *Number of Responses:* 8; *Total Annual Hours:* 24. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650).

Dated: December 12, 2017.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017-27048 Filed 12-14-17; 8:45 am]

BILLING CODE 4120-01-P**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2017-N-0809]

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 (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-vjbk), 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.

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-vjbk), manufactured by Ultragenyx Pharmaceutical, Inc., meets the criteria for a priority review voucher. MEPSEVII (vestronidase alfa-vjbk) 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/DevelopingProductsforRareDiseases/Conditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about MEPSEVII (vestronidase alfa-vjbk), 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.

[FR Doc. 2017-27049 Filed 12-14-17; 8:45 am]

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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