Dated: April 29, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–09007 Filed 5–2–19; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–1619]**

### List of Patient Preference-Sensitive Priorities; Establishment of a Public Docket; Request for Comments

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of the list of patient preference-sensitive priorities on FDA's website entitled, ''Patient Preference-Sensitive Areas: Using Patient Preference Information (PPI) in Medical Device Evaluation.'' As part of FDA's commitments for the reauthorization of the Medical Device User Fee Amendments of 2017 (MDUFA IV), the Center for Devices and Radiological Health (CDRH) committed to publish a list of priority areas where preference-sensitive data can inform regulatory decision making. FDA is also establishing a docket to solicit public input on this list of preference-sensitive areas that may impact the design and conduct of premarket medical device clinical studies, benefit-risk assessments, and postmarket evaluation.

**DATES:** Submit either electronic or written comments on the notice by July 2, 2019 to ensure that the Agency considers your comment on the list of patient preference-sensitive priorities.

**ADDRESSES:** You may submit comments on this notice 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 Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for 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–2019–N–1619 for ''List of Patient Preference-Sensitive Priorities; Establishment of a Public Docket; Requests for Comments'' 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.

**FOR FURTHER INFORMATION CONTACT:** Anindita Saha, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5414, Silver Spring, MD 20993–0002, 301–796–2537.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In 2016, the FDA issued guidance entitled, ''Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling—Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders'' (Ref. 1), outlining how stakeholders, including industry and patient advocacy organizations, can voluntarily collect and submit PPI that may be used by FDA staff in regulatory decision making.

As part of FDA's commitment for the reauthorization of MDUFA IV), FDA committed to advancing patient input and involvement and to identify patient preference-sensitive priority areas that may inform regulatory decision making (Ref. 2). FDA seeks to successfully build on our strong commitment to patients by engaging them to understand and considering their experience and perspectives, as it relates to medical device clinical studies, benefit-risk assessments, and postmarket surveillance.

As such, on December 7–8, 2017, FDA cohosted a collaborative workshop with the Centers of Excellence in Regulatory Science and Innovation entitled, ''Advancing Use of Patient Preference Information as Scientific Evidence in Medical Product Evaluation'' (Ref. 3). This workshop discussed the current progress on incorporating PPI into

benefit-risk assessments and used case examples, explored PPI methods, and future research topics to improve the use of PPI in regulatory decisions.

Based on feedback attained during the workshop, FDA identified the following parameters to assist in the identification of the priority list of patient preference-sensitive areas for medical device review, where:

- FDA staff are looking to better understand the full impact of the disease or condition and treatment options on patients and/or caregivers;
- Patients may value the benefits and risks of a technology or treatment differently from healthcare professionals and/or caregivers;
- Population-level differences in patient perspectives are not well understood, due to differences in:
  - Demographic characteristics;
  - Stages of disease; or
  - Disease phenotype; and
- There is significant public health impact (such as high mortality or morbidity rates and high prevalence rates of the disease, or few treatment options available such as in rare diseases).

## II. Patient Preference-Sensitive Priority Areas

Based on the above parameters, FDA generated a list of priority preference-sensitive areas, and organized the areas into the following categories:

- Patient values in diagnosis and treatment;
- Relevant clinical endpoints for specific patient populations;
- Patient benefit-risk trade-offs for treatment options or diagnostic approaches; and
- Impact of uncertainty in the benefit-risk tradeoffs.

The current collated list of identified patient preference-sensitive areas can be found on the FDA website at *https://www.fda.gov/about-fda/cdrh-patient-engagement/priority-list-patient-preference-sensitive-areas*. The priorities listed on the web page may be broadly applicable to many diagnostic/therapeutic areas, while others are specific to a disease/condition or technology. This is not an exhaustive list of all patient preference-sensitive areas, and the prioritization of these areas may shift over time as health technologies and patient preference methodologies advance.

## III. Other Issues for Consideration

FDA is soliciting public input from interested persons on the identified priority list of patient preference-sensitive topics captured on the FDA website at *https://www.fda.gov/about-fda/cdrh-patient-engagement/priority-list-patient-preference-sensitive-areas*. In addition, FDA is interested in responses to the following questions:

1. Do any existing topics on the Priority List of Patient Preference-Sensitive Areas need to be refined to better represent patient preference-sensitive areas important to regulatory efforts? And, if so, how? Please provide an explanation to support any recommended refinements.

2. Are there other areas not listed on the FDA website at *https://www.fda.gov/about-fda/cdrh-patient-engagement/priority-list-patient-preference-sensitive-areas* that FDA should consider as priority patient preference-sensitive areas? If there are additional areas for consideration, please identify and provide an explanation for each additional area using the parameters outlined in Section I: Background.

3. Are there ongoing studies or published studies that adequately address any of these patient preference-sensitive areas in a regulatory context? If so, please provide information or references regarding the studies.

## IV. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov*. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling—Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-preference-information-voluntary-submission-review-premarket-approval-applications*.

2. MDUFA Performance Goals and Procedures, Fiscal Years 2019 through 2022, available at *https://www.fda.gov/media/102699/download*.

Advancing Use of Patient Preference Information as Scientific Evidence in Medical Product Evaluation Workshop at *https://www.fda.gov/science-research/advancing-regulatory-science/advancing-use-patient-preference-information-scientific-evidence-medical-product-evaluation*.

Dated: April 29, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–1262]**

### Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. 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 issuance of vouchers as well as the approval of products redeeming a voucher. FDA has determined that ULTOMIRIS (ravulizumab-cwvz) approved December 21, 2018, meets the redemption criteria.

**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: 301–796–9858, email: *althea.cuff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that ULTOMIRIS (ravulizumab-cwvz) approved December 21, 2018, meets the redemption criteria.

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 ULTOMIRIS (ravulizumab-cwvz) go to the ''Drugs@FDA'' website at *https://*