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)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: For questions regarding this document, contact Tom Modric, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Place, Rockville, Rockville, MD 20855, 240–402–5853, *tomislav.modric@fda.hhs.gov* or *AskCVM@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 12, 2018 (83 FR 10732), FDA published the notice of availability for a draft guidance entitled ''Proprietary Names for New Animal Drugs,'' giving interested persons until May 11, 2018, to comment on the draft guidance. FDA received comments on the draft guidance, and those comments were considered as the guidance was finalized. Changes made include revisions to the definitions. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated March 2018.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on proprietary names for new animal drugs. 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.

III. Paperwork Reduction Act of 1995

FDA concludes that there are no collections of information under the Paperwork Reduction Act of 1995. This guidance refers to previously approved collections of information found in FDA regulations. 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. 3501–3521). The collections of information in 21 CFR part 514 have been approved under OMB control numbers 0910–0032 and 0910–0699; the collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: May 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11679 Filed 5–29–20; 8:45 am]

BILLING CODE 4164–01–P

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 NURTEC ODT (rimegepant), approved February 27, 2020, 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 NURTEC ODT (rimegepant), approved February 27, 2020, 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 NURTEC ODT (rimegepant), approved February 27, 2020, go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: May 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11681 Filed 5–29–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0837]

Rare Disease Clinical Trial Networks; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the establishment of a docket to obtain information and comments from patients, patient advocates, the scientific community, health professionals, other regulatory and health authorities in the global community, regulated industry, and the general public regarding practical steps and successful approaches to establish a rare disease clinical trials network.

DATES: Submit written or electronic comments and information on the notice by July 31, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 31, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 31, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2019–N–5464 for ''Rare Disease Clinical Trial Networks; Request for Information and Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.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.

FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring, MD 20993–0002, 240–402–6525, *meghana.chalasani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Over the past decade, progress has been made in planning and conducting clinical trials for rare disease drug development. In 2018, for the first time ever, a majority of new molecular entities approved by the FDA were orphan drugs to treat rare diseases. However, of the approximately 7,000 known rare diseases, less than 10 percent have an FDA-approved treatment available. Rare disease drug development continues to be challenged by the small numbers of patients and limited understanding of the variability and progression of each disease.

To support innovation and quality in the drug development pipeline for rare diseases, FDA has proposed establishment of a ''Rare Disease Cures Accelerator.'' The Rare Disease Cures Accelerator would provide a more centralized infrastructure and common platform(s) and approaches to support: (1) Rare disease characterization, (2) development of standard core sets of clinical outcome assessments and endpoints relevant to rare conditions, and (3) support conduct of clinical trials in rare disease populations. Following FDA CDER receipt of $10 million in FY 2019 Congressional appropriations for investment and innovation for rare diseases, FDA launched a set of efforts to begin building capabilities for the first two of these three components. To learn more, please visit FDA's Rare Disease Cures Accelerator Homepage [*https://www.fda.gov/drugs/regulatory-science-research-and-education/rare-disease-cures-accelerator*].

With this request for information and comments, FDA is interested in understanding what work is currently being done and what work needs to be done to address the third component of its Rare Disease Cures Accelerator—improving the design, conduct, and completion of rare disease clinical trials. FDA is particularly interested in learning practical steps and successful approaches related to startup, implementation, and sustainment of clinical trials networks for rare diseases, including specific considerations for establishing such networks for a range

of rare diseases. Because of the small size of rare disease populations and global occurrence of rare conditions, it is considered that the networks needed to support rare disease drug development would also have global reach and operations.

II. Requested Information and Comments

FDA requests input on practical steps and successful approaches to startup, implement, and sustain global clinical trials networks, including specific considerations for establishing such networks for a range of rare diseases. Questions that could be addressed include, but are not limited to, those listed below. It is not necessary to answer all the questions below.

1. What should be the immediate (<3 years) and long-term objectives of a global clinical trials network?
2. How could a global clinical trials network for rare disease be organizationally structured (*e.g.,* what mix of scientific and clinical disciplines are engaged to staff it; what process or guidance is followed for study protocol design; what standard procedures are employed for conduct of trials, and related protection of study participants and study data, etc.)? For example:
- Are there experiences that can be shared regarding networks integrating a disease-specific development center with a disease-agnostic operations center?
- Are there experiences that can be shared regarding networks focused on a broad group of rare diseases and collaboration with regional or disease-specific networks?

3. What kind of investigator experience is needed to start up and expand to implement a global clinical trial network (*e.g.,* experience with clinical trial research administration, clinical trial operations, working with pharmaceutical companies in the design, conduct and management of clinical trials)?
4. What are successful models of governance for global clinical trial networks (*e.g.,* role, responsibilities, and composition of various governing bodies)?
5. What are potential opportunities to leverage and/or complement other existing networks (*e.g.,* Institute for Advanced Clinical Trials for Children Network, Duke Clinical Research Institute Pediatric Trial Network, National Institutes of Health (NIH) Rare Diseases Clinical Research Network, NIH Experimental Therapeutics Clinical Trials Network, European Network of Paediatric Research at the European Medicines Agency)?
6. What infrastructure is required to startup, implement, and sustain a global clinical trials network (*e.g.,* required administrative, financial and physical resources, centralized functions, data coordination and network operations, global interoperability)?
7. What level of funding would be needed to establish a network, potentially expand a network, and sustain the network over the long term (*e.g.,* at least 5 years and longer)? A a range of estimates (*e.g.,* startup costs, annual operating costs) and associated assumptions would be helpful.
8. What are the key milestones and associated timelines for starting up and expanding to implement a global clinical trials network?
9. What are potential challenges or barriers to starting up, implementing, and sustaining a global rare disease clinical trials network?

Dated: May 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11655 Filed 5–29–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1069]

Approved Drug Products With Therapeutic Equivalence Evaluations (the ''Orange Book''); 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 Agency) is announcing the establishment of a public docket to solicit comments on FDA's publication entitled ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (commonly known as the ''Orange Book''). The Orange Book identifies drug products approved by FDA under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and includes related information. As part of FDA's Drug Competition Action Plan and our continued effort to improve transparency and provide useful information to regulated industry and the public, we are seeking comments on how stakeholders and the public use the Orange Book and whether it can be improved.

DATES: Submit either electronic or written comments by August 31, 2020.

ADDRESSES: You may submit comments 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–2020–N–1069 for ''Approved Drug Products With Therapeutic Equivalence Evaluations (the 'Orange Book'); Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see ADDRESSES), 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