performed its core functions, independent of project-specific outcomes.

We do have some concerns regarding (1.b.1). Discuss CAC involvement in evaluating UCEDD activities, and in the development and review of the final program progress report.

At every CAC meeting, we provide updates on the UCEDDs activities, where CAC members are encouraged to comment and make suggestions. An in-depth annual report is provided at our full-day in person CAC meeting every November. If that coincides with a five-year renewal application earlier that year, then a 5-year cumulative report is shared.

Previously, there has been no requirement for CAC members to be directly involved in the development of this report. Essentially, this is a technical report, aggregating 5- years' worth of NIRS data with additional narrative and impact statements. As such, we feel it is both burdensome and somewhat irrelevant to involve the CAC in the development of a report that is submitted to AoD. Rather than ask about CAC involvement in the development, perhaps it would be more beneficial and direct to require that CAC members be surveyed about their experiences and satisfaction with the structure and function of their respective CACs over the preceding 5 years.

Response #4

Regarding Part (1.b1): ACL reviewed and accepts your recommendation to delete the requirement for CAC involvement in the development of the final five-year report.

Comment # 5

Recommend ensuring enough time is allocated between the year 5 annual report due date and the due date of the overall 5-year report.

Response # 5

The year 5 annual report is due July 30 and the 5-year closeout report is due 90 days after the end of the grant period or September 30 for time allocation.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
UCEDD Annual Report	67	1	1,462	97,954

Dated: May 21, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–11685 Filed 5–29–20; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0626]

Proprietary Names for New Animal Drugs; Guidance for Industry; 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 a final guidance for industry #240 entitled ''Proprietary Names for New Animal Drugs.'' This guidance provides recommendations to help new animal drug sponsors develop proprietary names for new animal drugs that do not contribute to medication errors, negatively impact safe use of the drug, or misbrand the drug. This guidance proposes a framework for evaluating proposed proprietary names before submitting them for review by the Center for Veterinary Medicine (CVM or we). It also explains how new animal drug sponsors can request that CVM evaluate a proposed proprietary name.

DATES: The announcement of the guidance is published in the **Federal Register** on June 1, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2018–D–0626 for ''Proprietary Names for New Animal Drugs.'' 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.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]

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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.