

approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that IMCIVREE (setmelanotide) injection, manufactured by Rhythm Pharmaceuticals, Inc., meets the criteria for a priority review voucher. IMCIVREE (setmelanotide) injection is indicated for the treatment of chronic weight management in adult and pediatric patients 6 years of age and older with proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency obesity confirmed by genetic testing demonstrating variants in *POMC*, *PCSK1*, or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance.

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 <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about IMCIVREE (setmelanotide) injection, go to the "Drugs@FDA" website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: December 14, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-27760 Filed 12-16-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0520]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited From Use in Animal Food or Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each

proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the recordkeeping requirements for substances prohibited from use in animal food or feed.

DATES: Submit either electronic or written comments on the collection of information by February 16, 2021.

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 February 16, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 16, 2021. 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-2013-N-0520 for "Substances Prohibited From Use in Animal Food or Feed." 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, 240-402-7500.

- **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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White

Flint North, 10A–12M, 11601
Landsdown St., North Bethesda, MD
20852, 301–796–7726, [PRASStaff@
fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Substances Prohibited From Use in Animal Food or Feed—21 CFR Part 589
OMB Control Number 0910–0627—
Extension

This information collection supports Agency regulations regarding substances prohibited from use in animal food or feed. Bovine spongiform encephalopathy (BSE) is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as

transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. Our regulation at § 589.2001 (21 CFR 589.2001), entitled “Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy,” is designed to further strengthen existing safeguards against the establishment and amplification of BSE in the United States through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals. These materials are referred to as “cattle materials prohibited in animal feed” or CMPAF. Under § 589.2001, no animal feed or feed ingredient can contain CMPAF. As a result, we impose requirements on renderers of specifically defined cattle materials, including reporting and recordkeeping requirements. For purposes of the regulation, we define a renderer as any firm or individual that processes slaughter byproducts; animals unfit for human consumption, including carcasses of dead cattle; or meat scraps. Reporting and recordkeeping requirements are necessary because once materials are separated from an animal it may not be possible, without records, to know whether the cattle material meets the requirements of our regulation.

Reporting: Under our regulations, we may designate a country from which cattle materials are not considered CMPAF. Section 589.2001(f) provides that a country seeking to be so designated must send a written request to the Director of the Center for Veterinary Medicine. The country is required to submit information about its BSE case history, risk factors, measures to prevent the introduction and transmission of BSE, and any other information relevant to determining whether the cattle materials from the requesting country do or do not meet the definitions set forth in § 589.2001(b)(1). We use the information to determine whether to grant a request for designation and to impose conditions if a request is granted. Section 589.2001(f) further states that countries designated under that section will be subject to our future review to determine whether their designations remain appropriate. As part of this process, we may ask designated countries from time to time

to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We may revoke a country’s designation if we determine that it is no longer appropriate. Therefore, designated countries may respond to our periodic requests by submitting information to confirm their designations remain appropriate. We use the information to ensure their designations remain appropriate.

Recordkeeping: Renderers that receive, manufacture, process, blend, or distribute CMPAF, or products that contain or may contain CMPAF, must take measures to ensure that the materials are not introduced into animal feed, including maintaining adequate written procedures specifying how such processes are to be carried out (§ 589.2001(c)(2)(ii)). Renderers that receive, manufacture, process, blend, or distribute CMPAF are required to establish and maintain records sufficient to track the CMPAF to ensure that they are not introduced into animal feed (§ 589.2001(c)(2)(vi)).

Renderers that receive, manufacture, process, blend, or distribute *any* cattle materials must establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with, or does not otherwise contain, CMPAF (§ 589.2001(c)(3)(i)).

Renderers that receive, manufacture, process, blend, or distribute *any* cattle materials must, if these materials were obtained from an establishment that segregates CMPAF from other materials, establish and maintain records to demonstrate that the supplier has adequate procedures in place to effectively exclude CMPAF from any materials supplied (§ 589.2001(c)(3)(i)). Records will meet this requirement if they include either: (1) Certification or other documentation from the supplier that materials supplied do not include CMPAF (§ 589.2001(c)(3)(i)(A)), or (2) documentation of another method acceptable to FDA, such as third-party certification (§ 589.2001(c)(3)(i)(B)).

Description of Respondents: Respondents to this information collection include rendering facilities, feed manufacturers, livestock feeders, and foreign governments seeking designation under § 589.2001(f).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
589.2001(f); request for designation	1	1	1	80	80
589.2001(f); response to request for review by FDA	1	1	1	26	26
Total					106

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
589.2001(c)(2)(ii); maintain written procedures	50	1	50	20	1,000
589.2001(c)(2)(vi) and (c)(3)(i); maintain records	175	1	175	20	3,500
589.2001(c)(3)(i)(A) and (B); certification or documentation from the supplier	175	1	175	26	4,550
Total					9,050

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 9, 2020.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27746 Filed 12–16–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0074]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA

regulations governing State enforcement notifications.

DATES: Submit either electronic or written comments on the collection of information by February 16, 2021.

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 February 16, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 16, 2021. 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–2018–N–0074 for “Agency Information Collection Activities; Proposed Collection; Comment Request; State Enforcement Notifications.” 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, 202–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be