

to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals to determine whether recall action is adequate. Failure to collect this information would prevent FDA from receiving timely information about devices that may have a serious effect on the health of users of the devices.

Reports of corrections and removals may be submitted to FDA via mail or using FDA's Electronic Submission Gateway (ESG). We estimate that approximately 99 percent of submitters will use the ESG. Our estimate of the

reporting and recordkeeping burden is based on Agency records and our experience with this program, as well as similar programs that utilize FDA's ESG.

For respondents who submit corrections and removals using the electronic process, the operating and maintenance costs associated with this information collection are approximately \$30 per year to purchase a digital verification certificate (certificate must be valid for 1 to 3 years). This burden may be minimized if the respondent has already purchased a verification certificate for other electronic submissions to FDA. However, FDA is assuming that all

respondents who submit corrections and removals using the electronic process will be establishing a new WebTrader account and purchasing a digital verification certificate. We therefore estimate the total operating and maintenance costs to be \$30,660 annually (1,022 respondents × \$30).

In the **Federal Register** of March 20, 2017 (82 FR 14367), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity (21 CFR part)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours <sup>2</sup>	Total operating and maintenance costs
Electronic process setup <sup>3</sup> .....	1,022	1	1,022	3.08	3,148	\$30,660
Submission of corrections and removals (part 806) .....	1,033	1	1,033	10	10,330	.....

<sup>1</sup> There are no capital costs associated with this collection of information.

<sup>2</sup> Totals may not sum due to rounding.

<sup>3</sup> We estimate that approximately 99 percent of respondents will submit corrections and removals using the electronic process. The actual burden hours for setup of the electronic process listed in the reporting burden table are divided by 3 to avoid double counting in the Office of Information and Regulatory Affairs Consolidated Information System. However, the one-time Average Burden per Response is 9.25 hours, resulting in a total one-time burden of 9,454 hours for the setup of the electronic process.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

Activity (21 CFR part)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records of corrections and removals (part 806) .....	93	1	93	10	930

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

Dated: June 20, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-N-0312]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA 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 the reporting requirements associated with extralabel drug use in animals.

**DATES:** Submit either electronic or written comments on the collection of information by August 25, 2017.

**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 August 25, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of August 25, 2017. 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-2008-N-0312 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Extralabel Drug Use in Animals.” 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.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:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** 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. “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.

#### Extralabel Drug Use in Animals—21 CFR Part 530 OMB Control Number 0910-0325—Extension

The Animal Medicinal Drug Use Clarification Act of 1994 allows a veterinarian to prescribe the extralabel use of approved new animal drugs. Also, it permits FDA, if it finds that there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to establish a safe level for a residue from the extralabel use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level (21 CFR 530.22(b)). Although to date, we have not established a safe level for a residue from the extralabel use of any new animal drug and, therefore, have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal and/or State Agencies, academia, or individuals.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
530.22(b), Submission(s) of Analytical Method .....	2	1	2	4,160	8,320

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

The burden for this information collection has not changed since the last OMB approval.

Dated: June 20, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-13296 Filed 6-23-17; 8:45 am]

**BILLING CODE 4164-01-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 Brineura (cerliponase alfa) manufactured by Biomarin Pharmaceuticals 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., Bldg. 22, Rm. 6484, Silver Spring, MD 20993-0002, 301-796-4061, FAX: 301-796-9858, email: [althea.cuff@fda.hhs.gov](mailto: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 Brineura (cerliponase alfa) manufactured by Biomarin Pharmaceuticals Inc., meets the criteria for a priority review voucher. Brineura (cerliponase alfa) is indicated to slow the progression of loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency.

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/DevelopingProducts/orRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about Brineura (cerliponase alfa) go to the “Drugs@FDA” Web site at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: June 20, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-13236 Filed 6-23-17; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-N-1066]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Annual Reporting for Custom Device Exemption**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by July 26, 2017.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0767. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Annual Reporting for Custom Device Exemption OMB Control Number 0910-0767—Extension**

The custom device exemption is set forth at section 520(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(b)(2)(B)). A custom device is in a narrow category of device that, by virtue of the rarity of the patient’s medical condition or physician’s special need the device is designed to treat, it would be impractical for the device to comply with premarket review regulations and performance standards.

The Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

- Devices created or modified in order to comply with the order of an individual physician or dentist;