until the new IC is approved and ready for usage.

The Older Americans Act (OAA) requires annual program performance reports from States, the District of Columbia, and Territories. In compliance with this OAA provision, ACL developed a SPR in 1996 as part of its National Aging Program Information System (NAPIS). The SPR collects information about how State Agencies on Aging expend their OAA funds as well as funding from other sources for OAA authorized supportive services. The SPR also collects information on the demographic and functional status of the recipients, and is a key source for ACL performance measurement. The information submitted by Title III grantees is AoA's principle source for data and information on programs and services funded under the Older Americans Act (OAA). The SPR serves as the Program Performance Report for the state grantees to meet their annual grantee reporting requirements and includes the data required by the OAA be reported in the AoA Annual Report to Congress. This IC is summary data of services for seniors provided or managed by State Units on Aging (SUA) and Area Agencies on Aging (AAA). Data is submitted annually by the 50 states, four Territories (American Samoa, Guam, Puerto Rico, and Virgin Islands), and Washington, DC. The SPR includes information on the number of people served, the number of units of specific services, Title III expenditures, total expenditures, number of state and local staff, number of providers, and major accomplishments.

Data from the SPR are the primary source for performance measures in the Congressional budget justification, the HHS Annual Performance Plan and Report as well as the Annual Report to Congress.

AoA also uses the data to respond to inquiries from stakeholders, the public, press, program and policy decision makers. Information from the most recent SPR is available on-line on the Aging Integrated Database (AGID). Results are available annually.

The proposed FY 2020 version posts on the ACL website link entitled *Proposed State Program Report (SPR) Form 2020 Revision* available at *https://acl.gov/programs/performance-older-americans-act-programs*

For review and comment on this proposed information collection request, please visit the ACL website *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden

ACL estimates the burden associated with this collection of information as follows: 2,750 annual burden hours.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
SPR	55	1	50	2,750
Total	55	1	50	2,750

Dated: August 20, 2019.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2019–18842 Filed 8–29–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–2991]

Pediatric Rare Diseases—A Collaborative Approach for Drug Development Using Gaucher Disease as a Model; Draft Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled ''Pediatric Rare Diseases—A Collaborative Approach for Drug Development Using Gaucher Disease as a Model; Draft Guidance for Industry; Availability'' that appeared in the **Federal Register** of December 7, 2017. The document announced the availability of a draft guidance focusing on drug development for pediatric patients with Gaucher disease. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Thursday, December 7, 2017 (82 FR 57759), in FR Doc. 2017–26357, the following correction is made:

On page 57759, in the first column, in the document heading and in the third column under *Instructions,* the docket number ''FDA–2017–N–6476'' is corrected to read ''FDA–2017–D–2991''.

Dated: August 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18730 Filed 8–29–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–E–0699 and FDA–2018–E–0705]

Determination of Regulatory Review Period for Purposes of Patent Extension; NERLYNX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for NERLYNX and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by October 29, 2019. Furthermore, any interested person may

petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by February 26, 2020. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 October 29, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 29, 2019. 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 Nos. FDA–2018–E–0699 and FDA–2018–E–0705 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; NERLYNX.'' 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product NERLYNX (neratinib), which is indicated for extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy. Subsequent to this approval, the USPTO received patent term restoration applications for NERLYNX (U.S. Patent Nos. 7,399,865 and 9,211,291) from Puma Biotechnology, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 5, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of NERLYNX represented the first permitted commercial marketing or use of the product. Thereafter, the

USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for NERLYNX is 5,102 days. Of this time, 4,738 days occurred during the testing phase of the regulatory review period, while 364 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 31, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was July 31, 2003.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* July 19, 2016. FDA has verified the applicant's claim that the new drug application (NDA) for NERLYNX (NDA 208051) was initially submitted on July 19, 2016.

3. *The date the application was approved:* July 17, 2017. FDA has verified the applicant's claim that NDA 208051 was approved on July 17, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 472 days or 1,826 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18816 Filed 8–29–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3130]

Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions; Guidance for Industry and Food and Drug Administration Staff; 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 entitled ''Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions.'' This guidance document describes FDA's current approach to considering uncertainty in making benefit-risk determinations to support certain FDA premarket decisions for medical devices—premarket approval applications (PMAs), De Novo requests, and humanitarian device exemption applications. This guidance document elaborates on the consideration of uncertainty as part of our overarching approach to a benefit-risk based framework that is intended to assure greater predictability, consistency, and efficiency through the application of least burdensome principles. This guidance also provides examples of how the principles for considering uncertainty could be applied in the context of clinical evidence and circumstances where greater uncertainty could be appropriate in premarket decisions, balanced by postmarket controls—PMAs for Breakthrough Devices and PMAs for devices for small patient populations.

DATES: The announcement of the guidance is published in the **Federal Register** on August 30, 2019.

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–3130 for ''Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions; Guidance for Industry and Food and Drug Administration Staff; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at