

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.

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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Margaret Kober, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5376, Silver Spring, MD 20993-0002, 301-796-0934.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS): Establishing Effectiveness of Drugs for Treatment." IC/BPS is a complex, poorly understood syndrome of unknown etiology. This draft guidance provides recommendations for establishing effectiveness for drugs intended to treat patients with IC/BPS. This draft guidance incorporates recommendations the FDA received at a December 2017 advisory committee meeting on trial design features (see the meeting material available at <https://www.fda.gov/advisory-committees/advisory-committee-calendar/december-7-2017-meeting-bone-reproductive-and-urologic-drugs-advisory-committee-12062017-12062017>), including enrollment criteria and acceptable efficacy endpoints for drugs intended to treat IC/BPS.

This draft guidance includes key considerations in trial design including enrollment criteria and efficacy endpoint selection. The draft guidance also provides general recommendations on design features and statistical considerations. This draft guidance also provides the FDA's current recommendations on the use of patient-reported outcome instruments to

evaluate patient symptoms to demonstrate a clinically meaningful change with treatment.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS): Establishing Effectiveness of Drugs for Treatment." 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.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections that 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 parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: November 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-26264 Filed 12-4-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-E-2596]

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

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 LUXTURNA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application 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 biological 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 February 3, 2020. 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 June 2, 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 February 3, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 3, 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-2018-E-2596 for “Determination of Regulatory Review Period for Purposes of Patent Extension; LUXTURNA.” 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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product LUXTURNA (voretigene neparvovec-rzyl). LUXTURNA is indicated for treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Subsequent to this approval, the USPTO received a patent term restoration application for LUXTURNA (U.S. Patent No. 9,433,688) from Trustees of the University of Pennsylvania, the University of Florida Research Foundation, Inc., and Cornell Research Foundation, Inc., and the

USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated May 13, 2019, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of LUXTURNA 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 LUXTURNA is 3,809 days. Of this time, 3,591 days occurred during the testing phase of the regulatory review period, while 218 days occurred during the approval phase. These periods of time were derived from the following dates:

- The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* July 18, 2007. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on July 18, 2007.

- The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* May 16, 2017. FDA has verified the applicant’s claim that the biologics license application (BLA) for LUXTURNA (BLA 125610) was initially submitted on May 16, 2017.

- The date the application was approved:* December 19, 2017. FDA has verified the applicant’s claim that BLA 125610 was approved on December 19, 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 application for patent extension, this applicant seeks 344 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: November 26, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.
[FR Doc. 2019–26252 Filed 12–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Autism Spectrum Disorder (ASD) Research Portfolio Analysis, NIMH

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: The Office of Autism Research Coordination, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9663, Room 6184, Bethesda, Maryland 20892 or can email your request, including your address to: iaccpublicinquiries@mail.nih.gov or nimhrapubliccomments@mail.nih.gov or can call Melba O. Rojas, NIMH, NIH at 301–402–0279. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on October 3, 2019, page 52888 (84 FR 52888) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been

extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: Autism Spectrum Disorder (ASD) Research Portfolio Analysis, NIMH, 0925–0682, expiration date 12/31/2019, EXTENSION, National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of the ASD research portfolio analysis is to collect research funding data from U.S. and international ASD research funders, to assist the Interagency Autism Coordinating Committee (IACC) in fulfilling the requirements of the Autism Collaboration, Accountability, Research, Education and Support (CARES) Act of 2019, and to inform the committee and interested stakeholders of the funding landscape and current directions for ASD research. Specifically, these analyses will continue to examine the extent to which current funding and research topics align with the *IACC Strategic Plan for ASD Research*. The findings will help guide future funding priorities by outlining current gaps and opportunities in ASD research as well as serving to highlight annual activities and research progress.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 714.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of projects per respondent	Average time per response (in hours)	Total burden hours
U.S. Federal	25	88	15/60	550
U.S. Private	9	63	15/60	142
Individuals/households—International Government	1	61	15/60	15
Individuals/households—International Private	2	13	15/60	7
Total		1434		714

Dated: November 27, 2019.

Melba O. Rojas,
Project Clearance Liaison, National Institute of Mental Health, National Institutes of Health.

[FR Doc. 2019–26260 Filed 12–4–19; 8:45 am]

BILLING CODE 4140–01–P