Correction

This Notice corrects a **Federal Register** Notice of Public Comment published on August 27, 2019, 84 FR 44899, page 44899–44900. The contact, title, email address, and fax number have been updated at page 44899, third column, lines 31–32, 37, and 39. (The deadline for submitting comments under the **DATES** section remains unchanged and is still September 26, 2019.) The corrected text is as follows for the **ADDRESSES** section:

ADDRESSES: Comments may be submitted to the attention of: Lauren Christopher, Director, Division of Energy Assistance, Office of Community Services, Administration for Children and Families, Department of Health and Human Services, 330 C Street SW, 5th Floor; Mail Room 5425, Washington, DC 20201. Alternatively, comments may be faxed to (202) 401–5642 or emailed to: *ocs@acf.hhs.gov.*

Statutory Authority: 42 U.S.C. 8626.

Elizabeth Leo,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2019–19310 Filed 9–5–19; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Intent To Award a Single-Source Supplement for the Centers for Independent Living (Subchapter C) Training & Technical Assistance (T&TA) Center Cooperative Agreement

ACTION: Announcing the intent to award a single-source supplement.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the Memorial Hermann Health System for training and technical assistance to the Centers for Independent Living (CILs) that are Subchapter C grantees. The purpose of this project is to develop and provide trainings for CILs, develop and provide TA to CILs, administer peer mentoring for CILs, and refer CILs to other T&TA resources. The administrative supplement for FY 2019 will be in the amount of $351,327, bringing the total award for FY 2019 to $1,634,490.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Regina Blye, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Disabilities, Office of Independent Living: telephone (202)-795–7374; email *regina.blye@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: The additional funding will not be used to begin new projects, but to serve more CILs that are Subchapter C grantees with the same services and opportunities that Memorial Hermann Health System has been providing for some CILs that are Subchapter C grantees.

Program Name: Centers for Independent Living (Subchapter C) Training & Technical Assistance (T&TA) Center.

Recipient: Memorial Hermann Health System.

Period of Performance: The supplemental award will be issued for the third year of the three-year project period of September 30, 2019 through September 29, 2020.

Total Award Amount: $1,634,490 in FY 2019.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: Rehabilitation Act of 1973, as amended, Public Law 114–95, Title 7, Section 721.

Basis for Award: The Memorial Hermann Health System is currently funded to provide T&TA to CILs for the period of September 30, 2017 through September 29, 2020. ACL is required to spend 1.8–2% of ACL's funds appropriated for CILs for FY 2020 on T&TA for CILs. Without this supplement, ACL would spend less than the 1.8% minimum required amount of funds on T&TA in FY 2020. This supplement will result in ACL complying with this minimum requirement of the statute. This additional funding will enable Memorial Hermann Health System to enhance its capacity to provide more trainings, technical assistance, peer mentoring, and referrals for more CILs.

Memorial Hermann Health System is uniquely positioned to complete the work called for under this project as Memorial Hermann Health System presently provides T&TA services to CILs. Many CILs have benefited from the T&TA provided by the Memorial Hermann Health System's many trainings and other resources.

Establishing another entity as a T&TA provider for CILs would probably be inefficient and disruptive. Another entity would not be able to promptly develop and implement a high-quality T&TA project for one year of funds. If this supplement were not provided, ACL would not meet the requirement that a minimum of 1.8% of funds appropriated for CILs be utilized to provide T&TA services to CILs.

Dated: August 30, 2019.

Lance Robertson,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2019–19248 Filed 9–5–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–E–1391]

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

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 SHINGRIX 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 November 5, 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 March 4, 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 November 5, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 5, 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 No. FDA–2018–E–1391 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; SHINGRIX.'' 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 SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted). SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older. Subsequent to this approval, the USPTO received a patent term restoration application for SHINGRIX (U.S. Patent No. 7,939,084) from GlaxoSmithKline Biologicals SA, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 18, 2018, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of SHINGRIX 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 SHINGRIX is 3,257 days. Of this time, 2,892 days occurred during the testing phase of the regulatory review period, while 365 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 (21 U.S.C. 355(i)) became effective:* November 21, 2008. The applicant claims November 24, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 21, 2008, which was the first date after receipt of the IND that the

investigational studies were allowed to proceed.

2. *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):* October 21, 2016. FDA has verified the applicant's claim that the biologics license application (BLA) for SHINGRIX (BLA 125614) was initially submitted on October 21, 2016.

3. *The date the application was approved:* October 20, 2017. FDA has verified the applicant's claim that BLA 125614 was approved on October 20, 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 1,361 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 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–19205 Filed 9–5–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0178]

Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Efficacy From Adults to Pediatric Patients 2 Years of Age and Older; 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 entitled ''Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Efficacy from Adults to Pediatric Patients 2 Years of Age and Older.'' The guidance provides recommendations to sponsors on the clinical development of drugs for the treatment of partial onset seizures (POS) in pediatric patients. Specifically, this guidance addresses FDA's current thinking regarding clinical development programs that can support extrapolation of the efficacy of drugs approved for the treatment of POS in adults to pediatric patients 2 years of age and older. This guidance finalizes the draft guidance entitled ''Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Efficacy from Adults to Pediatric Patients 4 Years of Age and Older'' issued on February 16, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on September 6, 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–0178 for ''Drugs for Treatment of Partial Onset Seizures: Full Extrapolation of Efficacy from Adults to Pediatric Patients 2 Years of Age and Older.'' 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