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#### C. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

#### IV. Submission Information

##### 1. Letter of Assurance

To receive funding, eligible entities must provide a Letter of Assurance containing all the information outlined in Section III above.

Letters of Assurance should be addressed to: Jennifer Johnson, Deputy Commissioner, Administration on Disabilities, Administration for Community Living.

Letters of Assurance should be submitted *electronically via email* to [PHWF@acl.hhs.gov](mailto:PHWF@acl.hhs.gov).

##### 2. Submission Dates and Times

To receive consideration, Letters of Assurance must be submitted by 11:59 p.m. Eastern Time on February 11, 2022. Letters of Assurance should be submitted *electronically via email* and have an electronic time stamp indicating the date/time submitted.

#### VII. Agency Contacts

##### 1. Programmatic and Submission Issues

Direct programmatic and submission inquiries to [PHWF@acl.hhs.gov](mailto:PHWF@acl.hhs.gov).

Dated: January 6, 2022.

Alison Barkoff,

Principal Deputy Administrator.

[FR Doc. 2022-00401 Filed 1-11-22; 8:45 am]

BILLING CODE 4154-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket Nos. FDA-2020-E-1817, FDA-2020-E-1818, and FDA-2020-E-1820]

##### Determination of Regulatory Review Period for Purposes of Patent Extension; ENHERTU; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) published a notice in the **Federal Register** of November 1, 2021, for the determination of a regulatory review

period for purposes of patent extension for the human biological product, ENHERTU. This document corrects that notice by adjusting the applicable regulatory review period for the testing phase and approval phase of the product, ENHERTU.

**DATES:** All due dates for submission of comments, redetermination requests, and submission of petitions for due diligence as well as the dates used to determine the regulatory review periods for the products noted above remain the same as originally published.

##### 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:** On November 1, 2021, the Food and Drug Administration (FDA or the Agency) published a notice in the **Federal Register** determining the regulatory review period for the human biological product ENHERTU. This correction to the notice adjusts the applicable regulatory review period of the product with the number of days occurring during the testing phase and the approval phase of the product ENHERTU.

##### Correction

In the **Federal Register** of November 1, 2021 (86 FR 60252), in FR Doc. 2021-23725, appearing on page 60253, in the third column, in section II., “Determination of Regulatory Review Period,” in the first two sentences, the following correction is made:

FDA has determined that the applicable regulatory review period for ENHERTU is 1,395 days. Of this time, 114 days occurred during the testing phase of the regulatory review period, while 1,281 days occurred during the approval phase.

Dated: January 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-00404 Filed 1-11-22; 8:45 am]

BILLING CODE 4164-01-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Health Resources and Services Administration

##### Updates to the Bright Futures Periodicity Schedule

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** Effective December 30, 2021, HRSA accepted recommended updates to the Bright Futures Periodicity Schedule, a HRSA-supported guideline for infants, children and adolescents for purposes of ensuring that non-grandfathered group and individual health insurance issuers provide coverage without cost sharing under the Public Health Service Act. The updates to the Bright Futures Periodicity Schedule are: A new category for sudden cardiac arrest and sudden cardiac death risk assessment, a new category for hepatitis B virus infection risk assessment, addition of suicide risk as an element of universal depression screening for children ages 12–21, and updated category title from “Psychosocial/Behavioral Assessment” to “Behavioral/Social/Emotional Screening,” with no revision to the ages in which the screening occurs (newborn to 21 years). Finally, two clarifying references related to dental fluoride varnish and fluoride supplementation have been added, with no associated recommended changes to clinical practice or health insurance coverage. Please see <https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html> for additional information.

##### FOR FURTHER INFORMATION CONTACT:

Savannah Kidd, M.S. MFT, HRSA/ Maternal and Child Health Bureau by calling 301-287-2601 or by emailing at [SKidd@hrsa.gov](mailto:SKidd@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** The Bright Futures program has been funded by HRSA since 1990. A primary focus of this program is for the funding recipient to maintain and recommend updates to the *Bright Futures Guidelines for Health Supervision of Infants, Children and Adolescents*, a set of materials and tools that provide theory-based and evidence-driven guidance for all preventive care screenings and well-child visits. One component of these tools is the Bright Futures Periodicity Schedule, a chart that identifies the recommended screenings, assessments, physical examinations, and procedures to be delivered within preventive checkups at each age milestone. Over the program’s existence, the Bright Futures Periodicity Schedule has become the accepted schedule within the United States for preventive health services through the course of a child’s development.

Section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13), added by the Patient Protection and Affordable Care Act (Pub. L. 111-148), requires that non-grandfathered group health plans and health insurance issuers offering