4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2020-E-2361; FDA-2020-E-2362; and FDA-2020-E-2363]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENSPRYNG; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is correcting a notice that appeared in the *Federal Register* of July 13, 2022. The document determined the regulatory review period for ENSPRYNG. After review of a timely request for reconsideration by the applicant of the calculation of the applicable regulatory review period of the biologic product ENSPRYNG in that notice, FDA has determined that a revision of the supplementary information section is warranted. This notice corrects the applicable regulatory review period language.

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:

In the *Federal Register* of July 13, 2022 (87 FR 41724), on page 41725, in the second column, under "II. Determination of Regulatory Review Period," the first two sentences should be corrected to read as follows: "FDA has determined that the applicable regulatory review period for ENSPRYNG is 2,494 days. Of this time, 2,128 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase."

Dated: May 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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