4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2024-E-0209 and FDA-2024-E-0210]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* on May 12, 2025. The document, entitled "Determination of Regulatory Review Period for Purposes of Patent Extension; ELREXFIO," announced the determination of the regulatory review period for ELREXFIO (elranatamab-bcmm) for purposes of patent extension. The document was published with only one of two docket numbers. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Jack Dan, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240-402-6940.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Monday, May 12, 2025 (90 FR 20177), in FR Doc. 2025-08256, the following corrections are made:

1. On page 20177, in the second column of the header of the document, "Docket No. FDA-2024-E-0210" is corrected to read "Docket Nos. FDA-2024-E-0209 and FDA-2024-E-0210."

2. On page 20177, in the ADDRESSES section, in the third column under Written/Paper Submissions, in the second and third lines of the Instructions paragraph, "Docket No. FDA-2024-E-0210" is corrected to read "Docket Nos. FDA-2024-E-0209 and FDA-2024-E-0210."

Dated: June 26, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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