4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2020-E-2333; FDA-2020-E-2334; FDA-2020-E-2336; and FDA-2020-E-2337]

Determination of Regulatory Review Period for Purposes of Patent Extension; ROZLYTREK INJECTION; 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* of July 8, 2022. The document announced the determination of the regulatory review period for ROZLYTREK INJECTION (entrectinib) for purposes of patent extension. The document was published with an incorrect dosage form. This notice corrects the dosage form of the drug product.

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:

Correction

In the *Federal Register* of July 8, 2022 (87 FR 40849), the dosage form for the human drug product ROZLYTREK (entrectinib), NDA 212726, is corrected from "INJECTION" to "CAPSULES" for all instances mentioned in the notice. Specifically, the drug product dosage form is corrected from "INJECTION" to "CAPSULES" in the following locations:

1. On page 40849, the following corrections are made:
    - In the second column, the title of the document is corrected to read: "Determination of Regulatory Review Period for Purposes of Patent Extension; ROZLYTREK

CAPSULES."

- In the second column, the first sentence under the SUMMARY section is corrected to read: "The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ROZLYTREK CAPSULES and is publishing this notice of that determination as required by law."
- In the third column, the first sentence under the section *Instructions* is corrected to read: "All submissions received must include the Docket Nos. FDA-2020-E-2333; FDA-2020-E-2334; FDA-2020-E-2336; and FDA-2020-E-2337 for 'Determination of Regulatory Review Period for Purposes of Patent Extension; ROZLYTREK CAPSULES.'"

2. On page 40850, the following corrections are made:

- In the second column, under section I. Background of the SUPPLEMENTARY INFORMATION section, the third paragraph introduction is corrected to read: "FDA has approved for marketing the human drug product, ROZLYTREK CAPSULES (entrectinib), NDA 212726, indicated for the treatment of:"
- In the second and third columns, under section I. Background of the SUPPLEMENTARY INFORMATION section, the last paragraph is corrected to read: "Subsequent to this approval, the USPTO received patent term restoration applications for ROZLYTREK CAPSULES (U.S. Patent Nos. 8,299,057; 8,673,893; 9,029,356; and 9,085,565) from Genentech, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated March 1, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ROZLYTREK CAPSULES represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period."

- In the third column, under II. Determination of Regulatory Review Period, the first sentence of the introductory paragraph is corrected to read: "FDA has determined that the applicable regulatory review period for ROZLYTREK CAPSULES is 1,968 days."
- In the third column, under II. Determination of Regulatory Review Period, the second sentence of the third paragraph is corrected to read: "FDA has verified the applicant's claims that the new drug application (NDA) for ROZLYTREK CAPSULES (NDA 212726) was initially submitted on December 18, 2018."

Dated: November 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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