



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-1227]

### Roerig Division of Pfizer Inc., et al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications; 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 July 21, 2020. The document announced the withdrawal of approval of 10 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of August 20, 2020. The document indicated that FDA was withdrawing approval of the following two ANDAs after receiving a withdrawal request from Kadmon Pharmaceuticals, LLC., 119 Commonwealth Dr., Warrendale, PA 15086: ANDA 076203, Ribavirin Capsules, 200 milligrams (mg) and ANDA 077456, Ribavirin Tablets, 200 mg, 400 mg, and 600 mg. Before FDA withdrew the approval of these ANDAs, Kadmon Pharmaceuticals, LLC. informed FDA that it did not want the approval of the ANDAs withdrawn. Because Kadmon Pharmaceuticals, LLC., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 076203 and 077456 are still in effect.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Correction**

In the *Federal Register* of Tuesday, July 21, 2020 (85 FR 44096), appearing on page 44096 in FR Doc. 2020-15727, the following correction is made:

On page 44096, in the table, the entries for ANDAs 076203 and 077456 are removed.

Dated: September 21, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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