



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1117]

Janssen Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 16 New Drug Applications; Correction

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* on May 14, 2020. The document announced the withdrawal of approval (as of June 15, 2020) of 16 new drug applications (NDAs) from multiple applicants. The document indicated that FDA was withdrawing approval of NDA 050641, Monodox (doxycycline monohydrate) Capsules, Equivalent to (EQ) 50 milligrams (mg) base, EQ 75 mg base, and EQ 100 mg base, after receiving a withdrawal request from Aqua Pharmaceuticals, LLC, 707 Eagleview Blvd., Suite 200, Exton, PA 19341. Before FDA withdrew the approval of NDA 050641, Aqua Pharmaceuticals, LLC, informed FDA that it did not want the approval of the NDA withdrawn. Because Aqua Pharmaceuticals, LLC, timely requested that approval of the NDA not be withdrawn, the approval of NDA 050641 is still in effect.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of May 14, 2020 (85 FR 28950), appearing on page 28950 in FR Doc. 2020-10367, the following correction is made:

On page 28951, in the table, the entry for NDA 050641 is removed.

Dated: August 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-19364 Filed: 9/1/2020 8:45 am; Publication Date: 9/2/2020]