4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0113]

Facta Farmaceutici S.p.A., et al.; Withdrawal of Approval of 23 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* of February 5, 2019. The document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, effective March 7, 2019. The document erroneously included ANDA 077895 for Ursodiol Capsules USP, 300 milligrams, held by Impax Laboratories, LLC. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993, 301-348-3035.

SUPPLEMENTARY INFORMATION:

Correction

In the *Federal Register* of Tuesday, February 5, 2019 (84 FR 1745), in FR Doc. 2019-01129, the following correction is made:

1. On page 1746, in the table, the entry for ANDA 077895 is removed.

In a separate notice published in this issue of the *Federal Register*, FDA is withdrawing the approval of ANDA 077895 under 21 CFR 314.150(d).

Dated: September 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-19920 Filed: 9/13/2019 8:45 am; Publication Date: 9/16/2019]