DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0390]

Lederle Laboratories et al.; Withdrawal of Approval of 12 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 May 12, 2021. The document announced the withdrawal of approval of 12 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of June 11, 2021. The document indicated that FDA was withdrawing the approval of ANDA 060164, Nystatin Ointment, held by Lederle Laboratories. However, the document published with an incorrect application number for this product. This document corrects that error.

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.

SUPPLEMENTARY INFORMATION: In the Federal Register of Wednesday, May 12, 2021 (86 FR 26058), appearing on page 26058 in FR Doc. 2021-09980, the following correction is made:

On page 26058, in the first column, in the first line in the table, the application number “060164” is corrected to read “061064”.

Dated: June 8, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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