4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA-2026-N-3445]

Egis Pharmaceuticals Limited, et al.; Withdrawal of Approval of Three Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of three abbreviated new drug applications (ANDAs) from the holders of those ANDAs. The basis for the withdrawal is that the ANDA holders have repeatedly failed to file required annual reports for those ANDAs.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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, 301-796-3471, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98).

In the *Federal Register* of December 29, 2025 (90 FR 60724), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of three ANDAs because the holders of these ANDAs had repeatedly failed to submit the required annual reports for these ANDAs. The holders of these ANDAs did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes a waiver of the opportunity for hearing by the holders of the ANDAs

concerning the proposal to withdraw approval of the ANDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the three applications listed in Table 1 of this document.

Table 1--Approved ANDAs for Which Required Reports Have Not Been Submitted

Application No.	Drug	Applicant
ANDA 060453	Bacitracin-neomycin sulfate-polymyxin B sulfate ointment with diperodon hydrochloride	Ambix Laboratories, 55 West End Rd., Totowa, NJ 07512
ANDA 074748	Captopril tablet, 12.5 milligrams (mg), 25 mg, 50 mg, and 100 mg	Egis Pharmaceuticals Ltd., 1475 Budapest 10 Pf. 100 Hungary
ANDA 074808	Piroxicam capsule, 10 mg and 20 mg	Do.

FDA finds that the holders of the ANDAs listed in Table 1 have repeatedly failed to submit reports required by §§ 314.81 and 314.98. In addition, under § 314.200, FDA finds that the holders of the ANDAs have waived the opportunity for a hearing and any contentions concerning the legal status of the drug products. Therefore, based on these findings and pursuant to the authority under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), approval of the ANDAs listed in Table 1 and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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