



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-3271]

Flamingo Pharmaceuticals Ltd.; Withdrawal of Approval of Two 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 two abbreviated new drug applications (ANDAs) from the holder of those ANDAs. The basis for the withdrawal is that the ANDA holder has 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DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 August 8, 2024 (89 FR 64936), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of two ANDAs because the holder of these ANDAs had repeatedly failed to submit the required annual reports for these ANDAs. The holder 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 holder 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 two 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 207309	Metronidazole tablet, 250 milligrams (mg) and 500 mg	Flamingo Pharmaceuticals Ltd., U.S. Agent for Flamingo Pharmaceuticals Ltd., 1125 Gaither Rd., Rockville, MD 20850
ANDA 207938	Piroxicam capsule, 10 mg and 20 mg	Do.

FDA finds that the holder of the ANDAs listed in table 1 has repeatedly failed to submit reports required by §§ 314.81 and 314.98. In addition, under § 314.200, FDA finds that the holder of the ANDAs has waived its 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*]**.

Dated: December 23, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024-31360 Filed: 12/30/2024 8:45 am; Publication Date: 12/31/2024]