4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2026-N-1224]**

# Masuu Global Solutions LLC, U.S. Agent for Extrovis AG, et al.; Withdrawal of Approval of 11 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 11 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Table 1.-- ANDAs for Which Approval Is Withdrawn

| Application No. | Drug | Applicant |
|---|---|---|
| ANDA 065366 | Azithromycin, tablet, Equivalent to (EQ) 500 milligram (mg) base | Masuu Global Solutions LLC, U.S. Agent for Extrovis AG, 2255 Glades Rd., Suite 324A, Boca Raton, FL 33431 |
| ANDA 078022 | Propranolol hydrochloride (HCl), extended-release capsule, 60 mg, 80 mg, 120 mg, and 160 mg | Do. |
| ANDA 090665 | Lidocaine HCl, injectable, 2% | Do. |
| ANDA 201530 | Methotrexate sodium preservative free, injectable, EQ 1 gram (gm) base/40 milliliters (mL) (EQ 25 mg base/mL) | Do. |
| ANDA 201689 | Ifosfamide, injectable, 1 gm/20 mL (50 mg/mL) and 3 gm/60 mL (50 mg/mL) | Do. |
| ANDA 203063 | Clindamycin palmitate HCl, for oral solution, EQ 75 mg base/5 mL | Do. |
| ANDA 203122 | Fluorouracil, cream, 0.5% | Do. |
| ANDA 203586 | Lamivudine, tablet, 150 mg | Breckenridge Pharmaceutical, Inc., 200 Connell Dr., Suite 4200, Berkeley Heights, NJ 07922 |
| ANDA 204430 | Riluzole, tablet, 50 mg | Cardinal Health Regulatory Sciences, U.S. Agent for Daito Pharmaceutical Co., Ltd., 7400 W 110th St., Suite 150, Overland Park, KS 66210 |
| ANDA 208643 | Paliperidone, extended-release tablet, 1.5 mg, 3 mg, 6 mg, and 9 mg | Lupin Pharmaceuticals, Inc., U.S. Agent for Lupin Limited, 400 Campus Dr., Somerset, NJ 08873 |
| ANDA 208817 | Oxycodone HCl, solution, 5 mg/5 mL | Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228 |

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, are hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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