

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910-0120
814, subparts A through E	Premarket approval	0910-0231
812	Investigational Device Exemption	0910-0078
“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”.	Q-submissions	0910-0756
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards.	0910-0755
56	Institutional Review Boards	0910-0130

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-10599 Filed 5-19-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0033]

Morton Grove Pharmaceuticals Inc. et al.; Withdrawal of Approval of Seven 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 March 5, 2021. The document announced the withdrawal of approval of seven abbreviated new drug applications (ANDAs) from multiple applicants as of April 5, 2021. The document indicated that FDA was withdrawing approval of the following five ANDAs, after receiving a withdrawal request from Neopharma, Inc., 211 College Road East, Suite 101, Princeton, NJ 08540: ANDA 078383, Pioglitazone Hydrochloride (HCl) Tablets, Equivalent to (EQ) 15 milligrams (mg) base, EQ 30 mg base, and EQ 45 mg base; ANDA 078953, Irinotecan HCl Injection, 40 mg/2 milliliters (mL) (20 mg/mL) and 100 mg/5 mL (20 mg/mL); ANDA 079049, Alendronate Sodium Tablets, EQ 5 mg base, EQ 10 mg base, EQ 35 mg base, and EQ 70 mg base; ANDA 090732, Anastrozole Tablets, 1 mg; and ANDA 203161, Irbesartan Tablets, 75 mg, 150 mg, and 300 mg. Before FDA withdrew the approval of these ANDAs, Neopharma, Inc., informed FDA that it did not want the approval of the ANDAs withdrawn. Because Neopharma, Inc., timely requested that approval of these ANDAs not be withdrawn, the approval

of ANDAs 078383, 078953, 079049, 090732, and 203161 is still in effect.

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 Friday, March 5, 2021 (86 FR 12950), appearing on page 12950 in FR Doc. 2021-04520, the following corrections are made on pages 12950 and 12951 in the table:

The entries for ANDAs 078383, 078953, 079049, 090732, and 203161 are removed.

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-P-0162]

Determination That NORMODYNE (Labetalol Hydrochloride) Injection, 5 Milligrams per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that NORMODYNE (labetalol hydrochloride) injection, 5 milligrams per milliliter (mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the

product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Christopher Koepke, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3600, *Christopher.Koepke@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).