



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-5935]

Intercept Pharmaceuticals, Inc., et al.; Withdrawal of Approval of New Drug Application for OCALIVA (Obeticholic Acid) Tablets, 5 Milligrams and 10 Milligrams, and Three Abbreviated New Drug Applications for Obeticholic Acid Tablets, 5 Milligrams and 10 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the new drug application (NDA) for OCALIVA (obeticholic acid) tablets, 5 milligrams (mg) and 10 mg, held by Intercept Pharmaceuticals, Inc., 305 Madison Ave., Morristown, NJ 07960 (Intercept). In addition, FDA is withdrawing approval of three abbreviated new drug applications (ANDAs) for obeticholic acid tablets, 5 mg and 10 mg, from three separate ANDA holders. Intercept voluntarily requested withdrawal of its NDA, and Apotex, Inc., Lupin Limited, and MSN Laboratories Private Limited voluntarily requested withdrawal of their respective ANDAs, under § 314.150(d) (21 CFR 314.150(d)). The expedited withdrawal procedures set forth in section 506(c)(3)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) have been waived.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants and their respective drugs and applications are included in the following table.

Table 1.--NDAs and ANDAs For Which Approval Is Withdrawn

Application No.	Drug	Applicant
NDA 207999	OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg	Intercept Pharmaceuticals, Inc., 305 Madison Ave., Morristown, NJ 07960 (Intercept)
ANDA 214862	Obeticholic Acid tablets, 5 mg and 10 mg	Apotex Inc., c/o Apotex Corp., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326 (Apotex)
ANDA 214980	Obeticholic Acid tablets, 5 mg and 10 mg	Lupin Limited, c/o Lupin Pharmaceuticals, Inc., 400 Campus Dr., Somerset, NJ 08873 (Lupin)
ANDA 215017	Obeticholic Acid tablets, 5 mg and 10 mg	MSN Laboratories Private Limited, c/o MSN Pharmaceuticals, Inc., 20 Duke Rd., Piscataway, NJ 08854 (MSN)

On May 27, 2016, FDA approved NDA 207999 for OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, under the accelerated approval pathway pursuant to section 506(c)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(c)(1) and 21 CFR 314.510). The accelerated approval of OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, for PBC, was subject to the requirement that Intercept conduct a postmarketing trial to verify and describe the clinical benefit of OCALIVA.

On May 26, 2021, FDA approved a safety labeling change to revise the indication of OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, to the treatment of adult patients with PBC without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with UDCA with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.

On May 30, 2023, FDA approved the ANDAs listed in table 1 for obeticholic acid tablets, 5 mg and 10 mg, for the conditions of use in the labeling of NDA 207999 for OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, the reference listed drugs on which these ANDAs relied.

On August 27, 2025, FDA notified Intercept of a potential problem with OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, (NDA 207999), specifically that the postmarketing trial did not verify clinical benefit and that OCALIVA-treated PBC patients in the postmarketing trial who had early-stage disease at baseline had an excess of liver transplants and deaths. FDA recommended that Intercept request withdrawal of approval of the NDA 207999 products under § 314.150(d) (21 CFR 314.150(d)). FDA also requested in follow-up correspondence sent on August 28, 2025, that Intercept waive the expedited withdrawal procedures set forth in section 506(c)(3)(B) of the FD&C Act.

On October 1, 2025, FDA notified Apotex of the potential problem with the drugs and recommended the applicant voluntarily request withdrawal of approval of ANDA 214862 for obeticholic acid tablets, 5 mg and 10 mg, under § 314.150(d) for the same reasons.

On October 1, 2025, FDA notified Lupin of the potential problem with the drugs and recommended the applicant voluntarily request withdrawal of approval of ANDA 214980 for obeticholic acid tablets, 5 mg and 10 mg, under § 314.150(d) for the same reasons.

On October 3, 2025, FDA notified MSN of the potential problem with the drugs and recommended the applicant voluntarily request withdrawal of approval of ANDA 215017 for obeticholic acid tablets, 5 mg and 10 mg, under § 314.150(d) for the same reasons.

On September 10, 2025, Intercept submitted a letter asking FDA to withdraw approval of NDA 207999 for OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, under § 314.150(d) and waiving the expedited withdrawal procedures set forth in section 506(c)(3)(B) of the FD&C Act. While noting disagreement with the Agency's assessment, Intercept explained that it respects the Agency's request and is proceeding in the interest of providing clarity to patients and prescribers.

In a letter dated October 3, 2025, Apotex requested that FDA withdraw approval of ANDA 214862 under § 314.150(d). In a letter dated October 10, 2025, Lupin requested that FDA withdraw approval of ANDA 214980 under § 314.150(d). In a letter dated November 15, 2025, MSN requested that FDA withdraw approval of ANDA 215017 under § 314.150(d). While

noting disagreement with the Agency's assessment, MSN acknowledged the public health reasons for the Agency's request and explained that its request for withdrawal is based on withdrawal of approval of the reference listed drug for ANDA 215017.

For the reasons discussed above, and in accordance with the applicants' requests, approval of NDA 207999 for OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg, and ANDAs 214862, 214980, and 215017 for obeticholic acid tablets, 5 mg and 10 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of Intercept's OCALIVA (obeticholic acid) tablets, 5 mg and 10 mg; Apotex's obeticholic acid tablets, 5 mg and 10 mg; Lupin's obeticholic acid tablets, 5 mg and 10 mg; and MSN's obeticholic acid tablets, 5 mg and 10 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d))).

Lowell M. Zeta,

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

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