No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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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DATES: Approval is withdrawn as of November 24, 2025.

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TABLE 1—NDAS AND ANDAS FOR WHICH APPROVAL IS WITHDRAWN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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Performance Review Board Members

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is publishing the names of the Performance Review Board Members (PRB) who are reviewing performance of Senior Executive Service members, Title 42 executives, Senior Level, and Scientific Professional employees for Fiscal Year 2025.

FOR FURTHER INFORMATION CONTACT: Dededrick Rivers, Program Manager, Executive Performance Management, Department of Health and Human Services, 330 C Street SW, Washington, DC 20201, (202) 389–2501.

SUPPLEMENTARY INFORMATION: Title 5, U.S.C. 4314(c)(4) of the Civil Service Reform Act of 1978 (Pub. L. 95–454) requires agencies to publish PRB member appointments in the **Federal Register**. HHS is appointing the following individuals to a roster for potential service on the Department's Performance Review Boards (PRBs) for calendar years 2025 and 2026.

The PRBs will review individual performance appraisals and organizational assessments for Senior Executive Service, Senior Level/Senior Technical, and Title 42 executive equivalent employees. Based on these reviews, the boards will recommend performance ratings and rating- based compensation to the HHS Secretary.

Last name	First name
ACOSTA	OLGA M.
ADAMS	STEVEN A.
AIYELAWO	PIUS A.
ALLEN	KIMBERLY M.
ALLEN	MICHAEL T.
ALMARAZ	SANTIAGO.
AMES	KAREN W.
AMIOTTE	JOSEPH H.
ANAEDOZIE	ONYEKACHUKWU C.
ANTHONY	ELISE S.
ARAMANDA	ALEXANDER F.
ARCHER	WILLIAM R.
ARCHEVAL	ANTHONY F.
ARMSTRONG	REBEKAH W.
ATENCIO	JILL L.
BABSKI	DIANNE P.
BALLANCE	CHRISTINA V.
BAUGH	CYNTHIA R.
BECKERMAN	PETER C.
BEGAY	DUWAYNE R.
BELL	WILLIAM D.
BENFORD	JOFFREY Q.
BENNETT	JASON E.
BENSON	KARI L.
BERGEVIN	DOUGLAS D.
BHARGAVA	DEEPAK.
BODDEN	CHERYL L.
BOOTH	JON G.
BOTTERILL	JULIE M.
BOULANGER	JENNIFER L.
BOVELL	STEPHANIE M.
BOWERS	TONYA E.
BOYLAN	MICHELLE M.
BRADWAY	COURTNEY B.
BRADY	MICHAEL P.
BRANDT	ERIN E.
BRANDT	KIMBERLY L.
BRATCHER-BOWMAN.	NIKKI R.
BRAUER	RANDY S.
BRAXTON	MAKOTO P.
BRILLMAN	DANIEL M.
BROOKS	JOHN H.
BROWN	MARK N.
BRUCE	DUANE N.
BRUCE	MELISSA J.
BUCKHAM	MATTHEW A.
BUCKLEY	VICKI E.
BULLS	MICHELLE P.
BURNS	WILLIAM S.
BURNSZYNSKI	JENNIFER C.
BUSH	LAINA M.
BUSH	MARGARET M.
BUZZELLI	MATTHEW J.
CABEZAS	MIRIAM G.
CANTWELL	KATHLEEN M.
CAPOZZOLA	CHRISTA A.
CARLTON	STEPHANIE J.
CARRION	SONYA M.
CARTER	CATHY T.
CASTAGNA	EVANGELYN L.
CHADWICK-GALLO	CARMELITA S.
CHAMP-GELBMANN	JANE M.
CHAPMAN	LYNDA W.
CHASAN SLOAN	DEBORAH M.
CHEE	DARLENE.
CHERTMAN	WILLY J.
CHESLEY	FRANCIS D.
CHILLAKURU	ANIL K.
CHON	KATHERINE Y.
CHONG	ZABEEN G.
CLASSAY	MICHELLE.
CLIFFORD	CHAD T.
COCHRAN	NORRIS W.
CODERRE	THOMAS R.
COLEMAN	KATHRYN A.
COLLINS	ROBIN R.
COMFORT	KAREN T.
CONROY	GLENDA J.
COOPER	FREDERICK L.
COOPER	RENEE L.
COPPENBARGER	CHRISTOPHER K.
COSTELLO	ANNE M.
COTTON	BEVERLY M.
COX	JORDAN P.
CRANSTON	SEANA C.
CRAVER	JAMES M.
CRAWFORD	GREGORY O.
CROCHUNIS	LEE A.
CRONIN	KELLY.
CUMMISKEY	KEVIN F.
CURTIS	JILLIAN E.
CUTHBERT	NATHANIEL W.
CZAJKOWSKI	JOHN B.
D SOUZA	IVOR L.
DANIELSON	TODD D.
DAVIS	KEVIN E.
DAVIS	NATHANIEL M.
DAY	JAMES.
DE LEON	DIANA F.
DECKER	PAIGE N.
DELONE	SARAH E.
DEMIRSOY	IPEK K.
DEMPSEY	ANTIGONE H.
DESAI	RUJUL H.
DEVOSS	ELIZABETH.
DEVOY	BRIDGET K.
DICKEY	AVIS D.
DILLARD	LISA A.
DISRAELLY	DEENA S.
DOOLEY	SEAN M.
DORAN	SAMUEL E.
DOWNS	TANETTE N.