

On September 10, 2025, Intercept submitted a letter asking FDA to withdraw approval of NDA 207999 for OCALIVA (obeticolic 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 (obeticolic acid) tablets, 5 mg and 10 mg, and ANDAs 214862, 214980, and 215017 for obeticolic acid tablets, 5 mg and 10 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of Intercept's OCALIVA (obeticolic acid) tablets, 5 mg and 10 mg; Apotex's obeticolic acid tablets, 5 mg and 10 mg; Lupin's obeticolic acid tablets, 5 mg and 10 mg; and MSN's obeticolic 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.

[FR Doc. 2025-20767 Filed 11-21-25; 8:45 am]

BILLING CODE 4164-01-P

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:

Dedrick 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.
BOWLAN	MICHELLE M.
BRADWAY	COURTNEY B.
BRADY	MICHAEL P.
BRANDT	ERIN E.
BRANDT	KIMBERLY L.
BRATCHER-BOWMAN	NIKKI R.

Last name	First name
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	CHICKY 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	GLENDIA 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.

Last name	First name	Last name	First name	Last name	First name
DRIGGS	SCOTT S.	JOHNSON	ALFRED C.	NICHOLLS	RICHARD J.
DRIVING HAWK	JAMES R.	JOHNSON	DAVID M.	NOELTE	KATE C.
DUPEE	JENNIFER M.	JOHNSON	JENNIFER D.	NOOKALA	MADHAVI L.
DUPRE	BRIAN A.	JOHNSON	JOHN A.	NOONAN	TIMOTHY R.
DURAN	VANESSA S.	JOHNSON	LENORA E.	NOVY	STEVEN D.
DURST	KELLEY A.	JOHNSTON	DARCIE L.	O CONNOR	JUDIT.
DUVALL	KEVIN M.	JOYNER	ARLENE R.	O'CONNELL	CHRISTOPHER M.
ECOFFEY	STACEY.	KAVANAGH	LAURA D.	OELSCHLAEGER	ALLISON M.
EDMONDS	AMANDA B.	KAWAZOE	ROBIN I.	OLSON	CAROLYN F.
ELDER	MARK D.	KEANE	THOMAS E.	OLSON	KAREN E.
ELLINGTON	RENATA D.	KECKLER	JUSTIN J.	O'NEILL	MARK P.
ENGELHARDT	TIMOTHY J.	KENNEDY	ELLIOT J.	OSTERHUES	ERIC J.
ENGELS	THOMAS J.	KEVENEY	SEAN R.	OXNER	JULIE A.
ESPIRITU	RACHELE C.	KIMBLE	ADRIENNE R.	PANCHOLI	MAMATHA S.
FABBRICATORE JR	JOHN E.	KLEIN	ROGER D.	PAPULA	DENNIS M.
FAENSON	INNA.	KLEINSCHMIDT	ARTHUR G.	PARISH	ELIZABETH E.
FAHEY	BRIAN M.	KLOMP	GERARD R.	PARKER HALVER- SON.	PAMELA.
FALLAHKHAIR	MICHAEL B.	KNAPP	CAPRICE A.	PASCOL	WILLIAM H.
FIGLIOLA	ANTHONY M.	KNOX	JOHN K.	PATTERSON	SARA S.
FINK	DOROTHY A.	KOUFOPOULOS	PETER N.	PERRY	TERRANCE W.
FISHMAN	ELIOT Z.	KOZMA	BETHANY A.	PESTORIUS	FREDERICK P.
FITZGERALD	DENIS J.	KRAM	ANTHONY S.	PETILLO	JOHN J.
FOGLER	SARAH.	KREPICH	CHRISTOPHER M.	PHILLIPS	RICHARD A.
FOSTER	ROBERT F.	KROOP	SETH R.	PIERCE	JULIA A.
FOWLER	LIESL I.	KROPA	HALLEY E.	PIKA	JOSEPH T.
FROHBOESE	ROBINSUE.	LANKFORD	DAVID W.	PLAUGHER	MARK J.
FRYE	DANIEL R.	LAROCHE	DARRELL W.	POOLE	CHRISTOPHER A.
FRYE	EUGENE F.	LATTA	EDWARD T.	POPE	KRISTIN M.
FULTON	CLAYTON W.	LAZARE	MARY M.	POSNACK	STEVEN.
GAIKOWSKI	DIXIE D.	LAZIO	JENNIFER L.	PRIETO	MOLLY O.
GALLOWAY	SUMMER E.	LEGIER	JAMIE W.	PRIGODICH	CHERYL E.
GARCIA	TAMYRA C.	LEIPHART	KRISTINE L.	PROTZEL BERMAN	PAMELA I.
GARDNER	JOHNATHAN J.	LEONARD	CONNIE L.	PURDUE	MICHELE L.
GARRITY	SHEILA R.	LIMAGE	JULIA E.	RABIN	BRIAN.
GAWALT	ANN G.	LIN	SUE C.	RACINE WELLS	LISA A.
GEIGER	REBEKAH E.	LIU	BETH C.	RANCOURT	ANNE R.
GHARPUREY	MADHULIKA M.	LONNERDAL	NILS D.	RATHGEB	COLLEEN C.
GILES	JOHN F.	LOWERY	AMBER E.	REAGAN	MELANIE A.
GOLDHABER	BEN L.	MABRY	SHIRLEY M.	REDFORD	DANA Y.
GOODGER	BRIAN K.	MACIAS	DANIEL.	RICE	GAREY R.
GOULDING	MICHAEL I.	MACRAE	JAMES.	RITTER	CHRISTINA S.
GRADISON	ANDREW K.	MAJEWSKI	LISA C.	RIVERA	RODNEY W.
GRAHAM	GRACE R.	MALONE	KEVIN P.	ROBINSON	SHEILA R.
GRECO KONE	REBECCA C.	MANTOAN	PATRICIA M.	ROBINSON	WILMA M.
GREENE	JONATHAN N.	MARTIN	CHRISTOPHER E.	ROLFES	ELLEN M.
GRIMSLEY	HEATHER S.	MARTINO	NICOLE H.	ROSAS	LUCILA G.
HAILSTONE	MITCHELL E.	MATHIS	J INGRID.	ROWAN	ALEXANDER K.
HALL	RANDALL J.	MAZANEC	BRIAN M.	RUDOLPH	NOEMI V.
HAMMARLUND	JOHN T.	MCCOY	QUENTIN T.	RUIZ	MARIA M.
HARIDOPOLOS	STEPHANIE E.	MCGILL	BRIAN T.	SAMPLES	WILLIAM R.
HARRIS	SHELLY R.	MCGOWAN	COLLEEN A.	SANFORD	BARBARA.
HAUCK	HEATHER L.	MCQUEEN	SHERRI G.	SCHARF BELL	HELGA M.
HAYES WALLER	BERNITA K.	MEDNICK	DAVID.	SCOTT	ALICIA R.
HEFFLER	STEPHEN K.	MENDOZA	MARTIN.	SCOTT	JOHN A.
HENDERSON	GRAEME S.	METER	ERIN M.	SCOTT	MARIE C.
HENDRIKSSON	MARLA.	METTLER	ERIK P.	SHANBHAG	KRISHNAKANT N.
HILL	KRISTI W.	MILLER	BEVERLY A.	SHAPIRO	JENNIFER R.
HOFFMANN	GEORGE C.	MILLER	COURTNEY L.	SHAPIRO	NEIL K.
HOGLE	MARK P.	MILLS	GEORGE G.	SHATTO	JOHN D.
HOLZERLAND	WILLIAM H.	MIMNAUGH	EMILY C.	SHIRDON	PATRICK A.
HONEY	KRISTEN T.	MINOR	CLARK D.	SHUY	CAITRIN M.
HOOVER	CAMILLE M.	MIRANDA	TERESA V.	SIGOUNAS	GEORGE.
HORN	DAVID C.	MITAL	MICHELE.	SINGLETON	SHANNON M.
HOWE	RORY C.	MONROE	MICHELLE A.	SKILES	DENNIS A.
HOWE	RYAN P.	MORRIS	THOMAS F.	SMAGH	KALWANT S.
HURD	RAYMOND B.	MOSHTAHEDIAN	ERICA D.	SMITH	BENNY L.
HUTCHINSON	KIM.	MUELLER	ERIN O.	SMITH	JENNIFER B.
HUTTINGER	ALEXANDRA L.	MULCAHY	GERARD J.	SMITH	LAURIE J.
IBARRA PRATT	ELENITA Y.	MURPHY	BRADEN J.	SMITH	MARISA.
INMAN	REESE C.	MYERS	ELISABETH C.	SMITH	MICHAEL W.
IWUGO	JENEEN M.	NAIR	SUMA.	SMITH	PHILLIP B.
JACKSON	SHANNON C.	NELSON	MAY D.	SORIANO	JOHN D.
JOHN	HANOCK P.	NELSON	PETER J.	SPEAR	STEFANIE N.
JOHN	KURT E.	NEWBOLD	PATRICK.		

Last name	First name
SPITALNIC	PAUL I.
STANNARD	PAULA M.
STEVENS	MARK D.
SUPPLEE	LAUREN H.
SUTTON	ABRAHAM J.
SUTTON	ERIN E.
SUVA	JERRY F.
SWYGERT	TIFFANY T.
TABE-BEDWARD	HENRIETTA A.
TAGALICOD	ROBERT S.
TAKASH	ANDREA M.
TAMMERO	MICHAEL A.
TARTAKOVSKY	MICHAEL.
TAYLOR	CAROLYN C.
THOMAS	FRED.
THOMAS	TISON V.
THORNBRUGH	MITCHELL L.
TIGNOR	BETH B.
TOMOYASU	NAOMI J.
TOTA	KENNETH T.
TOVEN	JEFFREY P.
TRAUTMAN	TRACEY J.
TRAVERSE	SCOTT B.
TRESS	DEBORAH W.
TRIBBLE SPENCER	KELLY R.
TRITZ	KAREN L.
TURNER	AMY J.
TWOHIE	ANNE-MARIE D.
VAN ABSHER	ELIZABETH S.
VASUDEVAN	SUNIL.
VAYDA	TARA L.
VERBETEN	JOHN E.
VERNO	MARTHA D.
VICENTE	WENDY S.
VITOLO	SARA M.
WAGNER	JOHN E.
WAKEFIELD	MARLENE E.
WALLACE	JULIA J.
WALLACE	MARY H.
WARD LUND	DEBRA L.
WEAHKEE	ROSE L.
WEAVER	BRENT.
WEAVER	GRETCHEN H.
WEIR	SHANA D.
WELLS	NATHAN T.
WENDEL	JENNIFER C.
WHEELAND	DANIEL G.
WILKINS	SHANITA L.
WILLIAMS	JEFFERY.
WILLIAMS	KEVIN D.
WILLIAMS	OLIVIA L.
WILLIAMS	RASHEED D.
WILLIS	NICOLE M.
WITKOFKY	NINA B.
WORSTELL	MEGAN L.
WRIGHT	DAVID R.
WU	JEFFREY C.
XAVIER	SOOSAI M.
YARBOROUGH	LA MONTE R.
YOUNG	LARRY D.
ZETA	LOWELL M.
ZORN	MATTHEW C.

Charles H. McEnerney III,

*Executive Director, Executive Resources
(Acting).*

[FR Doc. 2025–20731 Filed 11–21–25; 8:45 am]

BILLING CODE 4151–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Par Panel Topics in Clinical Care, Mental Health and Health Interventions Outcomes.

Date: January 28, 2026.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Christiane Robbins, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–867–5309, crobbs@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 19, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–20711 Filed 11–21–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Environmental Health Sciences; Cancellation of Meeting**

Notice is hereby given of the cancellation of the National Institute of Environmental Health Sciences Special Emphasis Panel, Draft NTP Developmental and Reproductive Toxicity Technical Report on 2-

Hydroxy-4-Methoxybenzophenone, December 1, 2025, 10:00 a.m. to December 1, 2025, 2:00 p.m., National Institute of Environmental Health Sciences, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709 which was published in the **Federal Register** on September 23, 2025, 90 FRN 45781.

Dated: November 19, 2025.

Denise M. Santeufemio,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–20755 Filed 11–21–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Adult Lifespan Psychopathology Study Section.

Date: January 8, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Benjamin Shapero, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–4786, benjamin.shapero@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)