UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Sun Pharma Advanced Research Co., Ltd. v. Becerra

Sun Pharma · No. Civil Action No. 2024-0946 (APM) · Decided December 1, 2025

SUMMARY

The court held that the FDA unlawfully denied Sun Pharma a rare pediatric disease priority review voucher after approving Sezaby, a treatment for neonatal seizures. It concluded that a drug application deemed approved under the transitional provisions of the 1962 FDA Amendments was not an application previously approved under the Hatch-Waxman pathways referenced in the voucher statute. The court granted Plaintiffs' motion for summary judgment and denied Defendants' cross-motion.

CASE DETAILS

COURT	United States District Court for the District of Columbia
WRITING FOR THE COURT	Amit P. Mehta
JURISDICTION	United States District Court for the District of Columbia
DECIDED	December 1, 2025
DOCKET	Civil Action No. 2024-0946 (APM)
DISPOSITION	other
PROCEDURAL POSTURE	Plaintiffs sought judicial review under the Administrative Procedure Act of the FDA's denial of a rare pediatric disease priority review voucher. The parties filed cross-motions for summary judgment on the administrative record.
STANDARD OF REVIEW	Under the APA, agency action must be set aside if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. The court exercised independent judgment over the statutory interpretation question and reviewed the agency's action on the administrative record as a question of law. Summary judgment under Federal Rule of Civil Procedure 56 does not independently govern APA claims.
PRECEDENTIAL VALUE	published
PARTIES	Sun Pharma Advanced Research Co., Ltd., Sun Pharmaceutical Industries, Inc. v. Robert F. Kennedy Jr., Secretary of Health and Human Services, United States Department of Health and Human Services, United States Food and Drug Administration

TOPICS

fda regulation | health law | judicial review of agency action | statutory interpretation | summary judgment

PRACTICE AREAS

health law | administrative law | FDA regulation | statutory interpretation | civil procedure

QUESTIONS PRESENTED

1. Whether an application that became effective by agency inaction under the original Food, Drug, and Cosmetic Act and was later deemed approved under the 1962 amendments constitutes an application containing an active moiety that was previously approved under 21 U.S.C. § 355(b)(1), (b)(2), or (j) for purposes of the Section 529 priority review voucher statute.
2. Whether the FDA acted contrary to law by denying Plaintiffs a rare pediatric disease priority review voucher based on NDA 000597.

HOLDINGS

1. An application that was merely deemed approved under the 1962 amendments, after becoming effective through agency inaction under the prior statutory regime, was not previously approved under 21 U.S.C. § 355(b)(1), (b)(2), or (j) for purposes of the Section 529 priority review voucher program.
2. The FDA acted contrary to law when it denied Plaintiffs a priority review voucher on the ground that phenobarbital sodium had been previously approved in NDA 000597.

KEY QUOTATIONS

> *"“Approval” in that context means a formal positive decision on an application by the FDA."* (9)

> *"A thing that is deemed to be something else does not become that something else."* (10)

> *"By cross-referencing the three Hatch–Waxman pathways in Section 529, Congress clearly signaled that any "previous approval" had to have successfully navigated one of the pathways."* (11)

> *"Accordingly, the court holds that NDA 000597 was not a "previously approved" application under "(b)(1), (b)(2), or (j)" of Section 505 for purposes of Section 529."* (12)

FACTUAL BACKGROUND

Plaintiffs received FDA approval in 2022 for Sezaby, a drug containing phenobarbital sodium for treating neonatal seizures, a rare pediatric condition. The FDA denied Plaintiffs a priority review voucher because it identified a 1939 application for a phenobarbital-and-atropine product, NDA 000597, which had been deemed approved under the 1962 amendments to the Food, Drug, and Cosmetic Act. NDA 000597 was never affirmatively approved based on substantial evidence of safety and efficacy; the FDA later determined that its effectiveness was unsupported, and formally withdrew the application in 1982. Sezaby was the first phenobarbital product identified in the opinion as having established efficacy for neonatal seizures.

PROCEDURAL HISTORY

The FDA approved Plaintiffs' drug Sezaby for treatment of neonatal seizures but denied Plaintiffs a priority review voucher because it determined that phenobarbital sodium had been previously approved in another application. Plaintiffs challenged that decision under the APA and moved for summary judgment. The court granted Plaintiffs' motion, denied Defendants' cross-motion, and denied as moot Plaintiffs' motion for judicial notice and to complete the administrative record.

DISPOSITION

other

REMAND INSTRUCTIONS

No specific remand instructions were stated. The court granted Plaintiffs' motion for summary judgment and held that the FDA acted contrary to law in denying the priority review voucher.

CASES CITED

- USV Pharm. Corp. v. Weinberger, 412 U.S. 655, 660-61, 663 (1973)
- Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 613-14 (1973)
- Cooper Lab'ys, Inc. v. Comm'r, 501 F.2d 772, 776 n.12 (D.C. Cir. 1974)
- Mylan Pharms., Inc. v. Sebelius, 856 F. Supp. 2d 196, 199-200 (D.D.C. 2012)
- Serono Lab'ys, Inc. v. Shalala, 158 F.3d 1313, 1316 (D.C. Cir. 1998)
- Otsuka Pharm. Co. v. Price, 869 F.3d 987, 989 (D.C. Cir. 2017)
- Mylan Lab'ys, Inc. v. Thompson, 389 F.3d 1272, 1274-75 (D.C. Cir. 2004)
- Loper Bright Enters. v. Raimondo, 603 U.S. 369, 394, 398-400 (2024)
- Env't Def. Fund v. EPA, 124 F.4th 1, 11 (D.C. Cir. 2024)
- Fed. Commc'ns Comm'n v. Prometheus Radio Project, 592 U.S. 414, 423 (2021)
- Solondz v. FAA, 141 F.4th 268, 276 (D.C. Cir. 2025)
- Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)
- Am. Biosci., Inc. v. Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001)
- Sierra Club v. Mainella, 459 F. Supp. 2d 76, 90 (D.D.C. 2006)
- City of Clarksville v. FERC, 888 F.3d 477, 482 (D.C. Cir. 2018)
- Novartis Pharms. Corp. v. Johnson, 102 F.4th 452, 460 (D.C. Cir. 2024)
- Wisconsin Cent. Ltd. v. United States, 585 U.S. 274, 284 (2018)
- Mead Johnson Pharm. Grp. v. Bowen, 838 F.2d 1332, 1336 (D.C. Cir. 1988)
- Sandoz Inc. v. Becerra, 57 F.4th 272, 274 n.1, 280 (D.C. Cir. 2023)
- Chao v. Russell P. Le Frois Builder, Inc., 291 F.3d 219, 229 (2d Cir. 2002)