United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 11, 2025 Decided August 25, 2026

No. 25-5137

NORWICH PHARMACEUTICALS, INC.,
APPELLANT

v.

ROBERT F. KENNEDY, JR., IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:25-cv-00091)

Andrew D. Prins argued the cause for appellant. With him on the briefs were *Rachael Westmoreland*, *Lia R. Barrett*, *Matthew S. Murphy*, and *Nicholas L. Schlossman*. *Margaret Dotzel* entered an appearance.

Gabriel Schonfeld, Attorney, U.S. Department of Justice, argued the cause for federal appellees. With him on the brief were *Brett A. Shumate*, Assistant Attorney General, and *Daniel Tenny*, Attorney. *Joshua Dos Santos* and *Benjamin C. Wei*, Attorneys, entered appearances.

Bryan M. Killian argued the cause for appellee Salix Pharmaceuticals, Inc. With him on the brief were *Douglas A.*

Hastings, *Brendan J. Anderson*, *Michael Abernathy*, and *Wan-Shon Lo*. *Colin S. Harris* entered an appearance.

Brian T. Burgess argued the cause for appellee Teva Pharmaceuticals USA, Inc. With him on the brief was *Sierra Perez-Sparks*.

Before: PILLARD, WALKER, and GARCIA, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* GARCIA.

GARCIA, *Circuit Judge*: Under the statutes governing the FDA's drug-approval process, the first company to submit a complete application for a generic version of a drug—thereby exposing itself to potential patent litigation from the brand-name drug maker—is typically rewarded with a 180-day period of marketing exclusivity. No competing generic can be sold until that period expires. To avoid unwarranted delays in generics coming to market, Congress also specified that these "first applicants" forfeit that exclusivity in certain circumstances. This case presents statutory interpretation questions about two such provisions, which concern the first applicant's "failure to market" or "failure to obtain tentative approval" from the FDA. We conclude that the FDA correctly interpreted the first but applied an incorrect causation standard for the second. We therefore affirm in part, reverse in part, and remand to the district court with instructions to remand to the agency for further proceedings.

I

A

The Food, Drug, and Cosmetic Act (FDCA) requires companies to secure FDA approval before selling "any new drug." 21 U.S.C. § 355(a). The new drug application process is typically "onerous and lengthy," *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013), requiring extensive

"scientific data showing that the drug is safe and effective," *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404 (2012). Developers of generic drugs, however, can submit an Abbreviated New Drug Application (ANDA). *Id.* at 404–05. An ANDA "piggy-back[s]" on the "evidence of safety and efficacy" that supported approval of the brand-name drug. *Id.* at 405. This process is "designed to speed the introduction of low-cost generic drugs to market." *Id.* The FDA generally approves the ANDA so long as the generic is, essentially, the equivalent of the brand-name version. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011); 21 U.S.C. § 355(j)(2)(A). But before that approval is finalized, the ANDA applicant must address patents associated with the brand-name drug that its generic might infringe.

Most brand-name drugs are covered by a variety of patents claiming—that is, asserting legal rights over—the drug itself or its methods of use. When a generic-drug applicant submits an ANDA, it identifies the brand-name drug its generic mimics and makes "certification[s]" as to each of the patents associated with that brand-name product. 21 U.S.C. § 355(j)(2)(A)(i), (vii). These certifications are identified by the paragraph numbers in Section 355(j)(2)(A)(vii) of the FDCA. As relevant here, a Paragraph IV certification attests that a patent covering the brand-name drug or a use of that drug "is invalid or will not be infringed" by the generic version. *Id.* § 355(j)(2)(A)(vii)(IV).

As an alternative to these certifications, the generic manufacturer can "submit a so-called section viii statement, which asserts that the generic manufacturer will market the drug for one or more methods of use not covered by the brand's patents." *Caraco*, 566 U.S. at 406 (citing 21 U.S.C. § 355(j)(2)(A)(viii)). If the generic manufacturer relies on a section viii statement, it "carves out" the patented methods of

use from its label and cannot market the drug for those purposes. *Id*.

Once the FDA concludes that a generic version is an adequate equivalent of the brand-name drug, the ANDA's certifications determine the effective date of approval. For example, if an applicant submits only Paragraph I or Paragraph II certifications, which indicate that patents for the brand-name drug were not filed or have expired, any approval will be effective immediately. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(II); *id.* § 355(j)(5)(B)(i). If an applicant submits an ANDA with Paragraph IV certifications, by contrast, approval is delayed to allow the patent holder to sue for patent infringement. *See id.* § 355(j)(5)(B)(iii); *see also* 35 U.S.C. § 271(e)(2)(A). If the patent holder sues within a specified period and that suit is successful, the FDA sets the effective date of approval for the generic as no earlier than the date the patent holder's last valid, infringed patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(II)(bb); 35 U.S.C. § 271(e)(4)(A). In the meantime, the ANDA can only be granted "tentative approval," which signifies that an ANDA otherwise meets the requirements for approval but cannot yet receive final approval because of a patent issue or, as discussed further below, a statutory exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA); 21 C.F.R. § 314.105(d).

The infringement suits brought by patent holders in response to Paragraph IV certifications are costly for the first generic applicant but can be immensely beneficial to subsequent generic-makers. If the first generic applicant proves that the brand-name drug's patents are invalid, for instance, the next ANDA submitted for a similar generic might avoid patent litigation entirely.

To "compensate . . . for research and development costs as well as the risk of litigation from patent holders," the statute

grants certain "first" applicants submitting an ANDA 180 days of marketing exclusivity. *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008); *see* 21 U.S.C. § 355(j)(5)(B)(iv). This incentive to be the first generic applicant "increase[s] competition by expediting the availability of generic[s]." *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010).

This same benefit can also create opportunities for anticompetitive practices. Brand and generic companies could—and, at times, did—collude to have an initial generic applicant delay its own marketing. And because the exclusivity period began only once that applicant commenced marketing, such a delay could in turn postpone market entry for all subsequent generics. *See Teva Pharms.*, 595 F.3d at 1316–17, 1317 n.5 (citing Fed. Trade Comm'n, Authorized Generics: An Interim Report ch. 2, at 1 (2009)). Congress revisited the first-applicant exclusivity scheme in 2003 to address that risk. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066; 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer) (discussing measures to "ensure" that first-applicant exclusivity "cannot be used as a bottleneck to prevent additional generic competition"). As part of that revision, Congress added a series of provisions describing when the first applicant would "forfeit" its marketing exclusivity, thereby allowing other generics to enter the market.

Two of the forfeiture provisions are at issue here.

The first, 21 U.S.C. § 355(j)(5)(D)(i)(I), concerns a failure to timely market the drug. As relevant here, a first applicant that submitted its ANDA more than 30 months ago will forfeit exclusivity if it does not market its drug within 75 days after at least one of several triggering events has occurred for "each of

the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period." *Id.* § 355(j)(5)(D)(i)(I)(bb). These triggering events include: a final court decision that the patent is invalid or not infringed; a settlement order or consent decree finding the patent is invalid or not infringed; or, in certain circumstances, the patent holder's withdrawal of patent information previously submitted to the FDA. *Id.*; *see Teva Pharms.*, 595 F.3d at 1317.

The second, 21 U.S.C. § 355(j)(5)(D)(i)(IV), concerns a failure to obtain tentative approval. A first applicant forfeits exclusivity if the FDA has not tentatively approved that applicant's ANDA within 30 months of filing. But the statute provides an exception that applies if "the failure [to obtain tentative approval] is caused by a change in or a review of the requirements for approval . . . imposed after the date on which the application is filed." *Id.*

If either forfeiture event occurs "with respect to" a particular first applicant, that applicant "shall" forfeit its marketing exclusivity. *Id.* § 355(j)(5)(D)(ii).

B

Salix Pharmaceuticals Inc. produces the drug rifaximin under the brand name Xifaxan. Rifaximin in its 550 mg form can treat irritable bowel syndrome with diarrhea (IBS-D) and hepatic encephalopathy (HE), a brain condition caused by severe liver disease; in its 200 mg form it can treat travelers' diarrhea. Actavis Laboratories FL, Inc., a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc., submitted an ANDA for 550 mg tablets of generic rifaximin on December 18, 2015, the first date any such application was submitted. *Norwich Pharms., Inc. v. Kennedy*, 2025 WL 1148463, at *5 (D.D.C. Apr. 18, 2025). Actavis's ANDA contained various

Paragraph IV certifications related to patents for the drug itself, its use to treat IBS-D, and its use to treat HE. *Id.*

Salix sued Actavis in March 2016 for patent infringement. *Id.* That litigation ended in a September 2018 settlement under which Actavis admitted its generic would infringe certain Salix patents, without conceding those patents' validity. *Id.* In exchange, Actavis obtained a license to market either an authorized generic approved by Salix or its own generic approved by the FDA no earlier than January 1, 2028. *Id*. That date was more than 22 months before the last of the Salix patents expires. *Id.* Despite the settlement, Actavis still needed FDA approval to market its generic version of rifaximin.

In 2017, just over a year after Actavis submitted its ANDA, the FDA published a revised draft of its guidance for rifaximin applications. The guidance recommended that applicants for the drug conduct additional "dissolution studies" to show "bioequivalence" with Xifaxan. *Id.* The FDA gave final approval to Actavis's ANDA approximately nine years later, on March 19, 2026. FDA's Fed. R. App. P. 28(j) Letter at 1 (Mar. 19, 2026).

While Actavis's ANDA remained pending before the FDA, Norwich Pharmaceuticals, Inc. submitted two ANDAs for rifaximin generics: No. 214,369 (ANDA '369) for a 550 mg dosage and No. 214,370 (ANDA '370) for a 200 mg dosage. Salix sued Norwich in March 2020 in the District of Delaware, alleging that ANDA '369 infringed several Salix patents, including No. '196, which covers features of the drug itself; No. '569, which covers the use of rifaximin to treat IBS-D; and No. '573, which covers the use of rifaximin to treat HE. *See* Compl. ¶¶ 19, 121, 141, *Salix Pharms., Ltd. v. Norwich Pharms., Inc.*, 2022 WL 3225381 (D. Del. Aug. 10, 2022). By the end of that case, Salix and Norwich had stipulated that

Norwich's ANDA '369 and "any amendments or supplements to [that] ANDA" did not infringe Patent No. '196. *See* J.A. 223–24. The Delaware District Court's final judgment subsequently determined that Patent No. '569 for IBS-D was invalid, but Patent No. '573—the HE patent—was both valid and infringed. *Salix*, 2022 WL 3225381, at *23. The Federal Circuit affirmed. *Salix Pharms., Ltd. v. Norwich Pharms. Inc.*, 98 F.4th 1056, 1069–70 (Fed. Cir.), *cert. denied*, 145 S. Ct. 567 (2024).[1]

While that appeal was pending before the Federal Circuit, Norwich amended its separate ANDA '370, which previously addressed only 200 mg rifaximin, to add the 550 mg dosage as well. As a result of this amendment, Norwich's ANDA '370 and Actavis's ANDA now both contain Paragraph IV certifications to Patent Nos. '196 and '569. But while Actavis submitted a Paragraph IV certification to the HE patent (No. '573), Norwich addressed that patent with a section viii statement asserting it would not market its generic as a treatment for HE, instead *only* marketing it as a treatment for IBS-D.

In January 2025, the FDA concluded that the 550 mg rifaximin tablets described in Norwich's ANDA '370 met the standard requirements for approval under the FDCA. *See Norwich Pharms.*, 2025 WL 1148463, at *7, *9. But the FDA

[1] The FDA issued only tentative approval for Norwich's ANDA '369. Norwich unsuccessfully challenged that decision. *See Norwich Pharms., Inc. v. Becerra*, 703 F. Supp. 3d 1 (D.D.C. 2023), *aff'd sub nom. Norwich Pharms., Inc. v. Kennedy*, 179 F.4th 48 (D.C. Cir. 2026). In the meantime, Salix has sued Norwich, alleging that No. '370 infringes its patents. *See* Compl. ¶¶ 33–61, *Salix Pharms., Inc. v. Norwich Pharms., Inc.*, No. 1:24-cv-7140-JFM (D.N.J. June 20, 2024). A motion for summary judgment is pending in that litigation.

also found that Actavis's ANDA was eligible for a 180-day exclusivity period that prevented it from granting Norwich's ANDA final approval. *Id.* at *9. The FDA rejected Norwich's arguments that Actavis had forfeited its marketing exclusivity. *Id.* at *8–9. The FDA therefore granted Norwich's ANDA '370 only tentative approval. *Id.* at *9.

C

Norwich filed this suit under the Administrative Procedure Act, alleging that the FDA's decision to grant tentative rather than final approval was arbitrary and capricious and contrary to law. Norwich also moved for a preliminary injunction. Salix, the brand-name drug's producer, and Teva Pharmaceuticals USA, Inc. (of which Actavis is a wholly owned subsidiary) intervened in support of the FDA. According to Norwich, Actavis had forfeited its first-applicant exclusivity by failing to timely market its generic and to timely obtain tentative approval from the FDA. At the parties' request, the district court consolidated consideration of the motion for a preliminary injunction with its consideration of the parties' motions for summary judgment. The court denied Norwich relief and granted the FDA's, Teva's, and Salix's cross-motions for summary judgment. *Norwich Pharms.*, 2025 WL 1148463, at *18.

The court agreed with the FDA that Actavis's 180-day exclusivity continued to block final approval of Norwich's ANDA No. '370. *Id.* at *15. In the court's view, the "natural reading" of the statutory text and structure establishes that triggering events required by the failure to market provision had not occurred for every "qualifying" patent certification, notwithstanding Norwich's HE carveout. *Id.* at *10–15. Turning to the failure to obtain tentative approval provision, the court concluded that Actavis's failure to obtain such approval by the statutory deadline was "caused by" the changes

in the March 2017 draft product-specific guidance. *Id.* at *17–18. The court agreed with the FDA that "caused by" in that provision did not require that the FDA's change be a but-for cause of Actavis's failure to obtain approval by the deadline. *Id.* Norwich appealed.

II

We review the district court's grant of summary judgment de novo. *AstraZeneca Pharms. LP v. FDA*, 713 F.3d 1134, 1138 (D.C. Cir. 2013). We ask, as the district court did, if there is any genuine dispute of material fact whether the FDA's decision was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* at 1138–39 (quoting 5 U.S.C. § 706(2)(A)). When that analysis involves statutory interpretation disputes, we "exercise [our] independent judgment" to "decid[e] whether an agency has acted within its statutory authority." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024).

Applying those standards, we conclude that the FDA correctly determined that Actavis has not forfeited its exclusivity under the "failure to market" provision in 21 U.S.C. § 355(j)(5)(D)(i)(I). But the agency applied the wrong causation standard for the "failure to obtain tentative approval" provision in 21 U.S.C. § 355(j)(5)(D)(i)(IV). Because of that error, the FDA must reassess whether Actavis forfeited its exclusivity under the failure to obtain tentative approval provision.

As a threshold matter, all agree that unless Actavis forfeited its exclusivity, its 180-day exclusivity period for rifaximin 550 mg would block final approval of Norwich's ANDA. Norwich's ANDA contains Paragraph IV certifications "and is for a drug for which a first applicant [Actavis] has submitted an application containing such a certification." 21 U.S.C. § 355(j)(5)(B)(iv)(I). Norwich

spills much ink insisting that Actavis's certification to the HE patent could not trigger that exclusivity provision on its own because Norwich's ANDA did not include a certification to that same patent. *See* Appellant's Brief 26–37. Actavis disagrees. Teva's Brief 37. But we need not decide whether only "matching" certifications trigger exclusivity under subparagraph (B)(iv)(I), because there is no dispute that Norwich's ANDA contains several certifications "matching" those in Actavis's ANDA. The crucial question is instead whether Actavis has forfeited that exclusivity.

A

We agree with the FDA and the district court that Actavis has not forfeited its exclusivity by failing to timely market its generic rifaximin drug.

Under the failure to market provision, a first applicant forfeits its exclusivity only if a triggering event—such as a final judicial decision that the patent at issue is invalid or not infringed—occurs "as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

The parties dispute whether Actavis's "qualifying" certifications include all Paragraph IV certifications in its ANDA that made it a first applicant, or only those certifications that reference the same patents as the Paragraph IV certifications Norwich included in its later-submitted ANDA '370. The FDA and Actavis argue the former "all certifications" view; Norwich urges the latter "matching certifications" view.

The dispute matters because, in Norwich's view, triggering events have occurred for each certification common

to the two ANDAs.[2] But all agree that no triggering event has occurred as to the HE patent for which Actavis's ANDA, but not Norwich's, includes a Paragraph IV certification. On Norwich's view, that fact is irrelevant because Actavis's certification to the HE patent was not "a certification qualifying the first applicant for the 180-day exclusivity period," and Actavis has forfeited its exclusivity period even if no triggering event has occurred for the HE patent.

We agree with the FDA and Actavis that the statutory phrase "a certification qualifying the first applicant for the 180-day exclusivity period" is best read to encompass each of the Paragraph IV certifications "contain[ed] and lawfully maintain[ed]" in the first applicant's ANDA. Accordingly, Actavis has not forfeited its exclusivity for failure to market until a triggering event occurs for each patent for which Actavis included a Paragraph IV certification in its ANDA—including the HE patent.[3]

The FDA's position fits the text of Section 355(j)(5)(D)(i)(I)(bb) and the provisions it references. The forfeiture provision focuses on the certifications "qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv)." To see what makes the first applicant qualified for—meaning, as the parties agree, eligible for—the exclusivity period, we look first to the statute's definition of the exclusivity period. That provision states that the "180-day exclusivity period" is "the 180-day period ending on the day

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[2] Intervenor Salix disputes that assertion. Salix's Brief 4. We need not and do not resolve that dispute.

[3] No party disputes that Actavis was the first to submit a substantially complete ANDA for rifaximin 550 mg, nor that its application "contain[ed] and lawfully maintain[ed]" the Paragraph IV certifications to Patent Nos. '196, '569, and '573. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb).

before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause." *Id.* § 355(j)(5)(B)(iv)(II)(aa). Standing alone, that language does not directly describe what makes an applicant eligible for marketing exclusivity. But it discusses that period as a benefit for which only a "first applicant" is eligible. And the statute defines a "first applicant" as "an applicant that on the first day on which a substantially complete application containing a [Paragraph IV certification] is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a [Paragraph IV certification] for the drug." *Id.* § 355(j)(5)(B)(iv)(II)(bb). That is, a first applicant is one who submits a substantially complete application before (or at the same time as) anyone else, with "a [Paragraph IV certification]." Just one Paragraph IV certification will do the trick and qualify the applicant as a "first applicant," and thus, for the exclusivity period.

Putting that all together: An ANDA applicant qualifies for the 180-day exclusivity period by being a first applicant for the drug at issue and qualifies as a first applicant by being the first to submit and maintain a Paragraph IV certification in a substantially complete ANDA. As a result, each Paragraph IV certification in a sufficiently timely and complete ANDA is "a certification qualifying the first applicant for the 180-day exclusivity period" for purposes of the failure to market provision. And a first applicant forfeits exclusivity under that provision only if a triggering event occurs "as to each" of those qualifying certifications.

Norwich counters, with some force, that the statutory text is not so straightforward. For instance, it emphasizes that the forfeiture provision refers to "a certification qualifying the first applicant for the 180-day exclusivity period *under subparagraph (B)(iv)*." *Id.* § 355(j)(5)(D)(i)(I)(bb). And if

we focus on subparagraph (B)(iv)(I), which describes how the 180-day exclusivity period operates, rather than (B)(iv)(II), which defines the "180-day exclusivity period" and "first applicant," Norwich's position appears plausible. The language in subparagraph (B)(iv)(I) is focused on the perspective of the subsequent application: If that application "contains a [Paragraph IV] certification . . . and is for a drug for which a first applicant has submitted an application containing such a certification," the subsequent application is subject to the 180-day exclusivity period. In Norwich's view, as previewed above, that "such a certification" language establishes a "relational" approach under which a first applicant's exclusivity period blocks only some subsequent applications—namely, those with Paragraph IV certifications to the same patents as the first application. Appellant's Brief 45–47. That "relational" approach, Norwich says, carries through to the forfeiture provision: Because the exclusivity period is "relational" and focused on overlapping certifications, the forfeiture provision's reference to those certifications "qualifying the first applicant for the 180-day exclusivity period" must be too, and triggering events are therefore required only for those overlapping certifications. Norwich also offers accounts of the statute's history and the drafters' policy objectives to support its position.

The appellees offer equally plausible rejoinders on these fronts. But we focus here on one point to which Norwich has no adequate response and which we find dispositive. However subparagraph (B)(iv)(I) functions—a question we do not resolve—the operation of the forfeiture provisions is clear in one key respect: First applicants are granted a single exclusivity period that is forfeited as to all subsequent applicants or not at all. There is no basis in the statute for Norwich's suggested "relational" or "partial" forfeiture of exclusivity. And because only the FDA's position fits that feature of the statute, it is the best reading.

Per the statute, "[t]he 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant." 21 U.S.C. § 355(j)(5)(D)(ii). This language—as the district court held and as the FDA, Actavis, and even Norwich emphasize—describes a single, indivisible exclusivity period: "*The* 180-day exclusivity period." *Id.* (emphasis added); *see Niz-Chavez v. Garland*, 593 U.S. 155, 166 (2021) ("using a definite article with a singular noun" implies a single, "discrete thing"). That language, moreover, is focused entirely on the first applicant, not anything about a subsequent application—exclusivity is "forfeited by a first applicant" and "with respect to that first applicant." The statute then describes a similarly indivisible consequence of that forfeiture: If "all first applicants forfeit the 180-day exclusivity period," then the exclusivity provisions no longer limit "approval of any application containing a [Paragraph IV] certification." 21 U.S.C. § 355(j)(5)(D)(iii). Again, the statute focuses on whether forfeiture events have occurred as to the first applicant, and provides that, if so, the applicant will have fully forfeited the exclusivity period.[4]

A statute that endorsed Norwich's view would need to be written quite differently. On its reading, the statute treats only those certifications in the first applicant's ANDA that match a certification in the subsequent applicant's ANDA as

[4] Indeed, the statute's forfeiture provisions largely address the first applicant and the status of its application. *See* 21 U.S.C. § 355(j)(5)(D)(i)(II)–(V) (describing forfeiture when a first applicant "withdraws" its application, "amends" all qualifying certifications, "fails to obtain tentative approval," or "enters into an agreement"). One forfeiture provision turns on the "expiration of all patents" to which the first applicant submitted a qualifying certification. *Id.* § 355(j)(5)(D)(i)(VI). None turns on the behavior or certification strategy of subsequent applicants.

"qualifying" certifications. If a triggering event occurred "as to th[ose] certifications," then the first applicant would forfeit its exclusivity as to that subsequent applicant, but not necessarily as to others. *See* Reply Brief 10; *see also* Appellant's Brief 46 ("The point of the forfeiture provision is to forfeit the 180-day exclusivity period under § 355(j)(5)(B)(iv)(I) *vis-à-vis the subsequent application*."). Applied here, that would mean that Actavis has forfeited its exclusivity period with respect to Norwich's ANDA, but not with respect to any ANDAs containing a Paragraph IV certification to the HE patent. The problem for Norwich is that there is no statutory basis for finding such partial forfeitures. To support Norwich's interpretation, instead of stating that a first applicant forfeits exclusivity "if a forfeiture event occurs with respect to that first applicant," 21 U.S.C. § 355(j)(5)(D)(ii), the statute would need provisions establishing that a first applicant can forfeit exclusivity "with respect to" particular subsequent applicants but retain it as to others. There are no such provisions.

As a result, we hold that *all* Paragraph IV certifications "contain[ed] and lawfully maintain[ed]" in the first applicant's ANDA are certifications "qualifying" the first applicant for exclusivity under Section 355(j)(5)(D)(i)(I)(bb). Because Actavis's ANDA included a Paragraph IV certification to the HE patent, and because there has been no triggering event for that patent, Actavis has not forfeited exclusivity under the failure to market provision.

B

Norwich separately argues that the FDA erred in determining that Actavis did not forfeit its exclusivity by failing to timely obtain tentative approval for its ANDA.

A first applicant forfeits the exclusivity period if it "fails to obtain tentative approval of the application within 30 months

after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed." 21 U.S.C. § 355(j)(5)(D)(i)(IV). Actavis's 30-month deadline was June 18, 2018, at which time its ANDA had not obtained tentative approval. But the FDA determined that Actavis had not forfeited its exclusivity because the statutory exception applied—the delay in approval was "caused by a change in or a review of the requirements for approval." *Id.* Specifically, the FDA concluded that its draft guidance for rifaximin ANDAs, released in March 2017, was "one of the causes" of Actavis's failure to obtain tentative approval. *Norwich Pharms.*, 2025 WL 1148463, at *17. The FDA maintained that "but-for causation" was not required. *Id.*

We hold that the FDA applied the wrong causation standard. The exception for failures to obtain tentative approval "caused by a change in or a review of the requirements" is best read to apply only if such a change or review is a but-for cause of the applicant's failure to timely obtain tentative approval. We remand for the agency to apply the correct causal standard in the first instance.[5]

1

The parties essentially dispute whether, and in what form, a but-for standard should apply. Under that standard, "an action 'is not regarded as a cause of an event if the particular event would have occurred without it.'" *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 347 (2013) (quoting W. Keeton et al., *Prosser and Keeton on the Law of Torts* 265 (5th ed. 1984)). Even where the but-for-causation standard

[5] Because we agree with Norwich that "caused by" incorporates a but-for causation analysis, we do not address its argument in the alternative regarding 21 U.S.C. § 355(q)(1)(G) and Salix's petition to the FDA regarding the criteria for rifaximin generics.

governs, however, courts sometimes apply an "exception" when "multiple sufficient causes independently . . . produce a result." *Paroline v. United States*, 572 U.S. 434, 451 (2014) (quoting *Burrage v. United States*, 571 U.S. 204, 214 (2014)); *see also* Dan B. Dobbs, Paul T. Hayden & Ellen M. Bublick, The Law of Torts § 189 (2d ed. Apr. 2026 update) (explaining that courts sometimes "drop the but-for test" if "each of two or more causes is sufficient standing alone to cause the plaintiff's harm").

A simplified example illustrates the difference: If a baseball game ends 3-0 after the winning team scores three solo home runs, no individual home run is a but-for cause of the outcome; had any single run not been scored, the team still would have won. But each home run is a sufficient cause of the result. *See Burrage*, 571 U.S. at 211–12, 214–15.[6]

Returning to the present context, imagine that the FDA has long required ANDAs to satisfy two hypothetical Requirements, 1 and 2. Each Requirement involves conducting a distinct type of study, and failure to conduct either one before the 30-month deadline would prevent approval. If an applicant failed to satisfy both Requirements by the deadline, each failure would be an independently sufficient cause of the FDA's consequent decision not to approve the ANDA. But neither failure would constitute a but-for cause. Failing to satisfy Requirement 2 is not a but-for cause because,

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[6] There can, of course, be multiple but-for causes of a single event. *See* Dobbs et al., *supra*, § 186 ("It is by no means true that the but-for test reduces everything to a single cause."). Consider another baseball game, this one ending 1-0 after the winning team hit a one-run home run. That home run is a but-for cause of the victory, as are "a host of *other* necessary causes, such as skillful pitching" and even "the league's decision to schedule the game." *Burrage*, 571 U.S. at 212.

even "without" that failure, the same result (no approval) would have occurred given the failure to satisfy Requirement 1—and vice versa. *See Nassar*, 570 U.S. at 347.

To bring the stakes of the parties' dispute into focus, imagine the same facts except that Requirement 2 was imposed just before the 30-month deadline, such that it constitutes "a change in . . . the requirements for approval" under 21 U.S.C. § 355(j)(5)(D)(i)(IV). Whether the first applicant can benefit from the forfeiture exception turns critically on whether the statute incorporates only strict but-for causation, or the exception for independently sufficient causes too. Under a strict but-for rule, the applicant's failure to timely obtain tentative approval was not "caused by" the FDA's change. Even if Requirement 2 was never imposed, the FDA would not have granted approval based on the applicant's failure to meet Requirement 1. Under the multiple-sufficient-causes exception, however, the applicant's failure to obtain tentative approval was "caused by" the change to Requirement 2. The applicant would therefore avoid forfeiture despite its separate failure to satisfy Requirement 1.

We hold that the phrase "caused by" in 21 U.S.C. § 355(j)(5)(D)(i)(IV) is best read to require a but-for analysis, without the exception FDA urges here. Although the statute does not define "caused by," the "requirement of but-for causation" is "part of the common understanding of cause" and so is "one of the traditional background principles against which Congress legislates." *Burrage*, 571 U.S. at 211, 214 (cleaned up). Across myriad contexts, courts have held that similar causal phrases such as "results from," "because of," "based on," and "by reason of" refer to but-for causation. *Id.* at 210–14. And the general rule is that courts deviate from that standard only where "textual or contextual indication[s]" suggest that but-for causation is inappropriate. *Id.* at 212; *see*

Sinclair Wyo. Refin. Co. LLC v. EPA, 114 F.4th 693, 708–09 (D.C. Cir. 2024).[7]

As the Supreme Court has explained, the exception for "multiple sufficient causes" is reserved for the "rare" instances when adherence to strict but-for causation would produce perverse results. *Burrage*, 571 U.S. at 214.

> To illustrate, if "A stabs B, inflicting a fatal wound; while at the same moment X, acting independently, shoots B in the head . . . also inflicting [a fatal] wound; and B dies from the combined effects of the two wounds," A will generally be liable for homicide even though his conduct was not a but-for cause of B's death (since B would have died from X's actions in any event).

Id. at 215 (quoting 1 W. LaFave, *Substantive Criminal Law* § 6.4(a), at 468 (2d ed. 2003)). Applying strict but-for causation in the situation of joint wrongdoers would have the absurd effect of allowing *both* to escape liability. As the Court put it in *Paroline v. United States*, 572 U.S. 434 (2014), courts have sometimes "departed from the but-for standard where circumstances warrant, especially where the combined conduct of multiple wrongdoers produces a bad outcome." *Id.* at 451;

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[7] We emphasize that we are presented with, and therefore reject, only the multiple-sufficient-causes exception the FDA has urged here. In a situation where the FDA changes multiple requirements, it might be appropriate to adopt a "variation" of the but-for test whereby multiple actions are "aggregated and considered as a whole." Dobbs et al., *supra*, § 189. In that situation, the but-for test could be applied to the "unit or set" of changes, and "[i]f the combined conduct is a but-for cause" of the resulting event, "then cause is established." *Id.* For example, in our hypothetical above, if *both* Requirements 1 and 2 were imposed just before the deadline, perhaps the combined "change" could be regarded as a but-for cause.

see also Dobbs et al., *supra*, § 189 (explaining that courts recognize independently sufficient causes where a strict but-for test would "violat[e] both an intuitive sense of causation and good legal policy" by giving "a windfall to [] negligent defendants"); *Restatement (Third) of Torts: Liability for Physical and Emotional Harm* § 27 cmt. c (A.L.I. 2010) (June 2026 update) ("A defendant whose tortious act was fully capable of causing the plaintiff's harm should not escape liability merely because of the fortuity of another sufficient cause."); Keeton et al., *supra*, 267 (similar).

The primary authority the FDA offers in support of importing the multiple-sufficient-causes exception here fits that same mold. In *Kilburn v. Socialist People's Libyan Arab Jamahiriya*, 376 F.3d 1123 (D.C. Cir. 2004), we interpreted a jurisdictional provision of the Foreign Sovereign Immunities Act. Under that provision, foreign sovereigns are not immune from damages suits for "personal injury or death" "caused by" violent acts such as "torture" and "extrajudicial killing." *Id.* at 1126. The foreign defendants argued that this provision required but-for causation. But that standard would have meant that if two state sponsors of terrorism jointly caused personal injury or death through a combination of independently sufficient acts, courts would have jurisdiction over *neither* of them. We rejected that argument, explaining that applying "a 'but-for' standard to joint tortfeasors could absolve them all," which is "precisely" the situation in "which courts generally regard 'but for' causation as inappropriate." *Id.* at 1129.

Here, however, there is no indication that departing from but-for causation in Section 355(j)(5)(D)(i)(IV) would best capture "congressional intent." *Paroline*, 572 U.S. at 458. Quite the opposite. The statutory baseline is that an applicant's failure to obtain tentative approval within 30 months warrants forfeiture. Applying a but-for causation

standard ensures that an applicant is excused from that failure only if that applicant would have timely secured tentative approval absent some relevant FDA "change in or . . . review of the requirements." 21 U.S.C. § 355(j)(5)(D)(i)(IV). Applying the exception for independently sufficient causes, by contrast, would "absolve" first applicants of their failure to secure tentative approval even if their ANDA included one or more critical deficiencies that would independently have prevented approval. *Kilburn*, 376 F.3d at 1129.

Return to our Requirement-1-and-2 hypothetical above: Suppose the first applicant simply could not, ever, meet Requirement 1. So it knows that it is barreling towards a forfeiture at the 30-month mark. But—through pure serendipity—the FDA changes Requirement 2 just before the 30-month deadline, and the first applicant is unable to timely comply with the revision. Under the FDA's rule, that change excuses the applicant's failure to receive approval, and thereby keeps subsequent applicants held up by the first applicant's exclusivity period, even though that applicant would not have received approval anyway. There is no reason to think Congress intended to grant deficient ANDAs that kind of windfall.[8]

The FDA's remaining arguments—its "longstanding" practice and the difficulty of conducting but-for analysis, FDA's Brief 45—do not undercut this conclusion. We do not defer to agency interpretations of statutes, particularly where, as with "caused by," the agency's "technical subject matter expertise" has "little to do with" the term in need of

[8] Indeed, deviating from strict but-for causation could conceivably undermine the statutory scheme in other ways. For instance, the FDA might delay improving its requirements if it knew that such changes might inadvertently preserve the exclusivity of a fundamentally deficient ANDA that would otherwise soon forfeit it.

clarification. *Loper Bright*, 603 U.S. at 402. Moreover, though we have no basis to doubt the FDA's assertions that a but-for rule will present additional complexities, we are confident the agency's experience with such applications will enable it to devise an administrable framework for assessing causation in a way consistent with the "best reading of the statute." *Id.* at 400.

2

Finally, we conclude that the FDA should conduct the but-for-causation analysis in the first instance. Norwich urges us to pursue and resolve that inquiry, but we decline to do so and instead follow our customary practice of "remand[ing] to the agency for additional investigation or explanation" in light of the agency's legal error. *FDA v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 587 (2025) (quoting *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985)).

According to Norwich, the outcome of a remand is "preordained" because the administrative record conclusively establishes that no change in or review of requirements caused Actavis's failure to obtain tentative approval, and the FDA has forfeited any argument to the contrary. Appellant's Supplemental Brief 8. We disagree.

Once the FDA determined that its March 2017 draft rifaximin-specific guidance was *a* cause of Actavis's failure to obtain tentative approval, it decided that it was "unnecessary to determine whether any additional bases for non-forfeiture exist[ed]." FDA's Supplemental Brief 11–12 (quoting J.A. 363); *see Norwich Pharms.*, 2025 WL 1148463, at *5. That is, the FDA never considered whether some "change in or review of" the requirements, *other* than the March 2017 guidance regarding "dissolution studies," was a but-for cause of Actavis's failure to obtain tentative approval. For that same reason, neither the FDA nor the intervenors forfeited the

argument that another change in or review of requirements satisfies this exception merely because they failed to raise it before the district court. Even if they had raised that argument, the district court could not have affirmed on a basis the agency itself did not articulate in the decision on review. *See SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943). Nor would that court have been able to adequately evaluate such an argument, had it been raised. To determine whether any other change in or review of requirements was the but-for cause of *Actavis*'s failure to obtain tentative approval, we would properly consult the record for *Actavis*'s application. *See* Salix's Supplemental Brief 10; *cf.* FDA's Supplemental Brief 1 n.1. Yet only the record for Norwich's ANDA '370 is before us in this case.

Because there is "uncertainty as to the outcome of [the] proceeding on remand," we decline to resolve the but-for causation analysis without giving the FDA the first opportunity. *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 24 (D.C. Cir. 2022) (quoting *Manin v. NTSB*, 627 F.3d 1239, 1243 n.1 (D.C. Cir. 2011)).

III

The district court's grant of summary judgment is affirmed in part and reversed in part. We affirm the court's rejection of Norwich's "failure to market" theory of forfeiture. We reverse its rejection of Norwich's "failure to obtain tentative approval" theory, and remand to the district court with instructions to remand to the FDA so that the agency may apply the but-for causation standard in the first instance.

So ordered.