

FORFEITURE OF 180-DAY EXCLUSIVITY

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180-Day Exclusivity: The Basics

Who Qualifies?:

1. First Applicant(s): “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.
2. First applicant status can be shared by multiple applicants, this is frequently the case.

How does 180-exclusivity function?:

1. 180-day exclusivity can be
   - -Triggered by first commercial marketing of the approved ANDA product(s) or marketing of an Authorized Generic(s)
   - -Relinquished by a First Applicant that is not yet approved
   - -Selectively waived by a First Applicant that has been approved and triggered exclusivity
   - -Forfeited-the subject of this panel discussion
2. FDA refrains from approving any subsequent applicants where 180-day exclusivity is held or potentially held by First Applicant(s) provided that 180-day exclusivity has not triggered and run, been relinquished, selectively waived, or forfeited.

Where can information on 180-day exclusivity be found?:

1. 180-day exclusivity that has been triggered can be found in the Orange Book which assigns a Patent Challenge(PC) code in the Orange Book corresponding to the day when 180-day exclusivity is no longer a barrier to approval for subsequent applicants
2. FDA’s Paragraph IV website which will contain information which covers the other scenarios.
3. In rare instances, FDA will publish letters and place them on its webpage titled Hatch-Waxman Letters.

SIX WAYS TO FORFEIT — § 355(j)(5)(D)(i)

Any one event causes that first applicant to forfeit. If all first applicants forfeit, no one gets it — exclusivity does not roll to the next filer.

(I) FAILURE TO MARKET

Later of: (aa) the earlier of 75 days after effective approval or 30 months after submission; and (bb) 75 days after a qualifying trigger has occurred as to each qualifying patent.

(aa) THE APPROVAL CLOCK

The earlier of
- 75 days after the first applicant's approval becomes effective, or
- 30 months after the ANDA was submitted

(bb) THE PATENT CLOCK

75 days after, as to EACH qualifying patent, one of:
- a final court decision of invalidity or non-infringement (in a case involving the first applicant or a tentatively approved later applicant)
- a settlement/consent order with a non-infringement or invalidity finding
- the NDA holder delists the patent

(IV) NO TENTATIVE APPROVAL

No tentative approval within 30 months of filing — unless caused by a change in or review of the requirements for approval

How FDA read "caused by" until August 2026: "FDA has determined that 'but-for' causation is not required … if one of the causes of failure to obtain tentative or final approval … was a change in or review of the requirements for approval … an applicant will not forfeit eligibility … notwithstanding that there may have been other causes."

(II) WITHDRAWAL

The first applicant withdraws the ANDA (or FDA deems it withdrawn)

(III) AMENDMENT

Every qualifying Paragraph IV certification is amended or withdrawn

(V) AGREEMENT

An agreement with another applicant, the NDA holder, or a patent owner that the FTC or a court finds unlawful

(VI) PATENT EXPIRY

All qualifying patents have expired

RIFXAMIN BACKGROUND: WHO FILED WHAT AND WHEN

Dec 18, 2015

Actavis (Teva) files ANDA 208959 — P-IV to every listed patent, incl. HE ’573. First applicant.

Mar 16, 2017

FDA grants Salix’s citizen petition in part; revised rifaximin PSG adds multi-pH dissolution to BE

Jun 18, 2018

Actavis’s 30-month tentative-approval deadline passes — no TA

Sep 2018

Actavis–Salix settlement: licensed entry Jan. 1, 2028 (or earlier if another generic launches)

Feb 2020

Norwich P-IV notice on ANDA 214369 (550 mg); Salix sues in D. Del. (Mar. 26, 2020)

Aug 24, 2021

FDA posts “Non-Forfeiture” for rifaximin 550 mg on the Paragraph IV list

Aug 10, 2022

D. Del. judgment: HE patents valid/infringed; § 271(e)(4)(A) — no approval of ’369 before Oct. 2, 2029

May 20, 2024

Norwich amends ANDA 214370 to add 550 mg — P-IV to IBS-D patents, § viii carve-out of HE ’573

Jan. 2025

FDA finds non-forfeiture and grants Norwich **tentative approval**

	Polymorph ’199 / ’206	IBS-D ’569 / ’667	Drug substance ’196	HE ’573
Actavis/Teva (first applicant, ANDA 208959)	Paragraph IV	Paragraph IV	Paragraph IV	Paragraph IV
Norwich (later filer, ANDA 214370)	Paragraph IV	Paragraph IV	Paragraph IV	§ viii carve-out
Asserted triggering event?	Yes — held invalid / expired	Yes — held invalid (Fed. Cir.)	Yes — non-infringement stipulation	NO — valid, infringed

FAILURE TO MARKET: AFFIRMED

HOLDING — FDA AFFIRMED

Norwich v. Kennedy, No. 25-5137 (D.C. Cir. Aug. 25, 2026) (Garcia, J., joined by Pillard & Walker, JJ.)

FORFEITURE IS ALL-OR-NOTHING

"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" (Slip op. 16)

IMPLICATIONS OF DECISION

1. Forfeiture requires a triggering event "as to each" qualifying patent; statute provides a first applicant with a single, indivisible exclusivity period, rather than exclusivity that may be forfeited on a patent-by-patent or subsequent-applicant-by-subsequent-applicant basis.

2. A Section viii carve-out does not remove a patent from the first filer's certification set. The carving applicant generally cannot itself generate a court trigger for that patent, so it must rely on another statutory trigger path. But "all Sec. viii" to qualifying patents does circumvent exclusivity. P3 + sec. vii could also defeat exclusivity.

3. Court left some uncertainty where there are nonmatching patent certifications.

FAILURE TO OBTAIN TENTATIVE APPROVAL: REVERSED

HOLDING — FDA REVERSED

Norwich v. Kennedy, No. 25-5137 (D.C. Cir. Aug. 25, 2026) (Garcia, J., joined by Pillard & Walker, JJ.)

THE COURT HELD THE CORRECT STANDARD IS BUT-FOR CAUSATION

"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." (Slip op. 19)

CONTRAST ILLUSTRATED: CONTRIBUTING VERSUS BUT-FOR CAUSATION

"FDA has long required Requirements 1 and 2; an applicant fails both at 30 months. Now suppose Requirement 2 was imposed just before the deadline. Under strict but-for, the change did not cause the failure — "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 FDA's exception, the change excuses it — "The applicant would therefore avoid forfeiture despite its separate failure to satisfy Requirement 1."

FACTORS THAT INFLUENCED THE DECISION

WINDFALL: *"Applying the exception for independently sufficient causes … 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. … There is no reason to think Congress intended to grant deficient ANDAs that kind of windfall."*

ADMINISTRABILITY IS NOT A DEFENSE: *"We are confident the agency's experience with such applications will enable it to devise an administrable framework for assessing causation."*

ONE CAVEAT: "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.'" (fn. 7)

TAKEAWAYS

Open Procedural Questions:

1. Will the D.C. decision Circuit stand after potential rehearing and/or appeal to the Supreme Court?
2. How will FDA implement but-for causation if the decision is not reversed?
3. How will FDA address the backlog of forfeiture determinations under the old standard?

IF YOU ARE THE FIRST FILER

- The “one of the causes” safe harbor may be gone. Any non-forfeiture that rested on a guidance change being merely a contributing cause now rests on a rejected standard.
- Your own deficiencies at the 30-month mark may now be dispositive evidence — would you have obtained TA absent the change?
- Build the aggregation argument (fn. 7) and the “review of” prong; document every FDA change and review touching the application.
- Exclusivity survives a long delay and does not run until launch — but watch the 30-day marketing-notice rule (§ 314.107(c)(2)).

IF YOU ARE A SUBSEQUENT FILER

- Forfeiture is indexed to the first filer’s certification set. Map it before you certify.
- A Section viii carve-out gives up the litigation trigger forfeiture route for that patent. To force a failure-to-market forfeiture you must clear every patent the first filer challenged.
- Winning forfeiture may still not get you to market: Paragraph III certifications, 30-month stays, and § 271(e)(4)(A) orders sit behind the exclusivity gate.
- You will litigate blind — the first filer’s record is confidential. Plan for a remand, not a judgment.

A “get out of jail free card”?

“There is no reason to think Congress intended to grant deficient ANDAs that kind of windfall.” — Slip Op. at 22.

Mean and median time to Tentative Approval for first-filed ANDAs containing at least one Paragraph IV certification

FY of Approval	Mean (Months)	Median (Months)	Number of ANDAs
2023	47.33	38.24	48
2024	44.86	36.29	43
2025	33.05	24.84	29

Source: *FDA Drugs@FDA dataset to identify the ANDAs and their approval statuses.*

Identified TAs: *Selected ANDA submissions with a current status of tentative approval dated 10/1/2022–3/31/2025. For ANDAs later finally approved, which no longer show a TA, I inferred TA dates from TA-named approval letters.*

Added detail: *Joined sponsor, product, and approval-letter with information the dataset lacks, such as first-to-file and submission/file acceptance dates, from public sources, including FDA’s Paragraph IV list and published TA/FA letters, or IPD Analytics.*

Straight-to-approval check: *Counted ANDAs with final approval in the window that appeared no tentative approval was ever granted.*

Average Number of Review Cycles to Approval – Complex Original ANDAs

Approval Fiscal Year	All	First Generic	Second or Later
2023	3.0	3.3	3.0
2024	3.3	3.15	3.3
2025	2.8	3.5	2.7

Source: *FDA Drugs@FDA dataset for every original ANDA full approval dated 10/1/2022–3/31/2025 and assigned fiscal years by approval date.*

Complex flag: *Applied FDA’s complex-product categories (GDUFA III and MAPP 5240.10) to dosage form, route and active ingredient.*

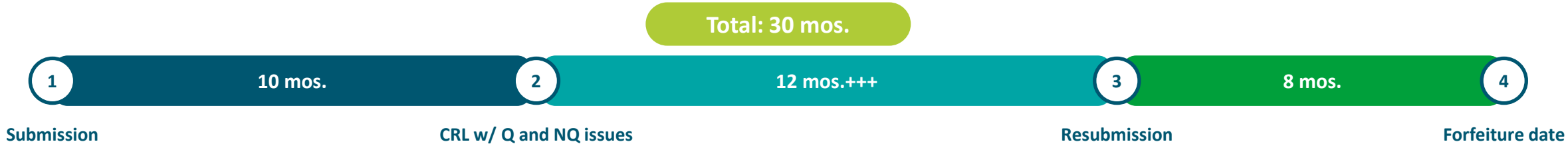
First-generic flag: *Used FDA’s First Generic Approvals lists for 2022–2025. All 199 entries dated in the window matched Drugs@FDA approvals.*

Submission dates: *Because Drugs@FDA does not publish submission dates, estimated each one from the ANDA number, which is assigned in sequence at receipt. Calibrated the estimates against the 120+ ANDAs in the Time to TA file with verified submission dates; typical error is about 40 days.*

Time to review end: *Measured from the estimated submission date to the tentative approval date where known, otherwise to final approval.*

Non-qualifying issues are not "independent"

"Remand would permit FDA to develop a framework for assessing but-for causation that—unlike Norwich's proposal—is administrable under these constraints. One possibility would be an approach that does not demand speculative reconstruction of a hypothetical ANDA review but focuses instead on any deficiencies that actually existed and would have prevented approval as of the first applicant's 30-month date. Under this approach, ***FDA could ask whether one or more such deficiencies were not excusable for forfeiture purposes because they did not relate to a change in or review of the requirements for approval***. Thus, if approval was precluded as of the 30-month date for one reason that could be traced to a change in or review of requirements, but was also precluded on another basis ***independent*** of any such change or review, ***FDA would conclude that a forfeiture occurred*** because on the statutorily relevant date, the excusable deficiency was not a but-for cause of the ANDA's non-approvability." — Gov't Supp. Br. at __ (emphases added)



21 CFR 314.110(a)(1): *"A complete response letter will describe all of the specific deficiencies that the agency has identified in an application or abbreviated application."*

21 CFR 314.110(b): *"After receiving a complete response letter, the applicant must take one of the following actions . . . Resubmit the . . . abbreviated application, addressing all deficiencies identified in the complete response letter."*

FDA regulations and the GDUFA process render all qualifying and non-qualifying issues "related" — non-qualifying issues are not "independent" if they needed to await identification to the applicant and then resubmission by the applicant **AT THE SAME TIME AS THE QUALIFYING ISSUES**.

For Discussion Purposes Only

"Requiring the agency to construct a completely impenetrable hypothetical counterfactual world…"

"Norwich would have FDA assess causation by first imagining that there was no change in the approval requirements for rifaximin and then attempting to reconstruct the hypothetical alternative timeline on which Actavis's ANDA would have been prepared, submitted, reviewed, revised, and approved. ***How fast, in other words, would Actavis have been able to produce an approvable application had there not been a change in approval requirements related to bioequivalence?***

Answering that question with something more than guesswork, however, would require extensive information about Actavis's internal capabilities and intentions that FDA does not have and cannot obtain. By law, FDA can only require an ANDA applicant to provide certain specified information about its proposed generic and the facilities that will produce it. ***FDA can do nothing but speculate, for example, as to what alternative manufacturing capacities might be available to an applicant if the agency is unsatisfied with those referenced in the ANDA, how long an applicant might take to produce new data at FDA's request, or how the answers to those questions might have been different in a hypothetical world where an approval requirement did not change during ANDA review.*** *But under Norwich's preferred version of but-for causation, those are exactly the answers at which FDA would be required to guess." — Gov't Supp. Br. at __ (emphases added).*

To articulate a standard that reflects the reality of GDUFA and maintains the Hatch Waxman balance, FDA would (1) identify at the 30-month mark all qualifying and non-qualifying issues and (2) assess the development and review processes holistically to determine what "caused" the failure to gain approval.

Critical to this assessment would be the timing of how the applicant and FDA addressed non-qualifying issues via DRLs, CRLs, resubmissions, etc.

For example, did the applicant or FDA delay the identification or resolution of non-qualifying issues because qualifying issues were being addressed?

This would be faithful to the Court's decision, as well:

"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.' 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.'" — Slip op. at __ fn.7 (citations removed)

GDUFA IV Changes and the Forfeiture 30-Month Clock

"Choose Your Own Adventure" Goal Date Extension Paradigm

- Strategic decision made at the beginning of each review cycle
- The single, 90-day extension provides predictability as to the action date but could potentially result in more CRLs

pOAI Alert Goal Date Extension

- Under GDUFA III, FDA would issue a CRL for an ANDA with a pOAI alert, necessitating a 5-month process for reclassification and review if the inspection were ultimately classified as NAI/VAI
- The goal date extension under GDUFA IV results in a moving target, though enables earlier approval action for an NAI/VAI inspection

Post-PAI Meeting Goal Date Extension

- The meeting is intended to address issues that FDA believes could be resolved in the review cycle and lead to an approval action
- There is the risk of a goal date extension, and applicants must consider where they are in the 30-month clock

Missed Goal Date Framework

- FDA will strive to issue *unrelated* IRs/DRLs by the goal date
- If but-for causation prevails, FDA will need to grapple with how these outstanding IRs/DRLs factor into the analysis