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FDA Calls For Limited Three-Year New Drug Exclusivity To Support Generics

Proposals On Biosimilars, 180-Day Generic Drug Exclusivity, And More

by Urtė Fultinavičiūtė

Something old, but also something new for generic drugs in the latest FDA's legislative proposal package.

Accompanying its $7.2bn budget request as part of the US president's fiscal year 2025 proposed budget, the Food and Drug Administration released its *latest legislative proposals* for generic drugs with a focus on amending certain exclusivity provisions.

While some of the items have been proposed by the US health agency a couple of times already, this year the FDA pointed to the amendment of the three-year exclusivity that is granted to new drugs in a bid to "encourage meaningful innovation and timely competition."

Under the current law, new drugs can qualify for exclusivity, which can block or delay competition from generic drugs, even if the applicant does not affirmatively seek it or "when the new clinical investigation that is the basis of exclusivity fails to demonstrate the hypothesized effect of the drug."

As such, the FDA proposed to amend the Hatch-Waxman three-year exclusivity provisions and offer it on a limited basis in "situations where the new drug applicant is actually seeking such exclusivity and where the data supporting the exclusivity demonstrates the hypothesized effect of the drug, and to prevent information on new safety risks from blocking competition."

"This approach would continue to reward innovation, while also allowing for earlier access to generic drugs in certain situations," the agency stated.

The FDA has been recently called out for its three-year new clinical investigation exclusivity by

the right-wing non-profit America First Policy Institute. The group stated that the FDA's policies, which favor drug manufacturers that bring new medications to market, are exploited by originator drugmakers through so-called strategic exclusivity evergreening. (Also see "*'America First' Non-Profit Points To USPTO And FDA For Patent Abuse*" - Generics Bulletin, 15 Feb, 2024.).

Eliminating Interchangeability Designation For Biosimilars

Another new addition to the FDA's request list is the proposed elimination of the interchangeability designation for biosimilars. Under the current law, approved biosimilars must receive this designation before they can be substituted for their reference product without consulting the prescribing physician.

This "has led to confusion and misunderstanding, including among patients and healthcare providers, about the safety and effectiveness of biosimilars and about whether interchangeable biosimilars are safer or more effective than other biosimilars," according to the document.

If the proposed change is accepted, biosimilars would "no longer include a separate statutory standard for a determination of interchangeability and to deem all approved biosimilars to be interchangeable with their respective reference products."

Biosimilar Interchangeability Designation Would Be Nixed Under Biden Proposal

By Derrick Gingery

12 Mar 2024

The proposal is not expected to cost or save the government money, but is expected to increase biosimilar uptake, according to budget documents.

Read the full article here

It is still unclear if these changes will happen soon, given that the proposed ideas touch on policies that the two political parties in the US disagree on (*see sidebar*).

More Clarity On Generic Drug 180-Day Exclusivity

In 2022, the FDA proposed an amendment to the 180-day exclusivity provisions that are granted to first generic applicants but fail to enter the market in 75 days. (Also see "*180-Day Exclusivity Changes Pushed In Biden's Budget Proposal*" - Generics Bulletin, 4 Apr, 2022.).

This year, the FDA reworded its proposal and sought to amend the "180-day exclusivity forfeiture provision regarding failure to market to specify that certain additional events can start the provision's 75-day period, possibly leading to forfeiture."

The agency stated that "the amendments would specify that the provision's 75-day period can be

triggered by the resolution of patent litigation without a finding of patent infringement or invalidity if there is no settlement agreement limiting the ability to market."

"Additionally, the amendments would provide that, when the terms of the resolution of patent litigation would allow the generic applicant to begin commercial marketing as of a certain date, the agreed-upon date would start the 75-day period leading to possible forfeiture."

The FDA hopes that this would help use its authorities more effectively and address exploitable loopholes in failure to market provision.

Same Proposals From Last Year

Along with the proposed changes on new drug exclusivity and biosimilar interchangeability, and added clarity to the 180-day exclusivity forfeiture, other legislative ideas set out this year have also been proposed by the agency previously. (Also see "*The Same But Different: Biden Budget Proposes Flexibility For Generic Drug-Device Combos, 'Skinny Labels'*" - Generics Bulletin, 15 Mar, 2023.).

For example, last year the FDA sought a legislative amendment to explicitly address the submission and review of abbreviated new drug applications for drug-device combination products and drug products submitted in an ANDA that are used with a device.

The agency also asked the US Congress to create a safe harbor for generic drug applications that market a product with a "skinny label" from patent infringement in the wake of the long-running litigation saga between *Teva* and *GSK*.

While a few weeks after the FDA request it seemed that Teva might have a chance of success (Also see "*Stage Set For Generics To Triumph With Skinny-Label Reversal*" - Generics Bulletin, 31 Mar, 2023.), it all came crashing down a few months later after the US Supreme Court refused to review the litigation (*see sidebar*).

The FDA also proposed a requirement to disclose the full ingredient list for brand drugs, including the amount of inactive ingredients in product labels, and allow the FDA to disclose that information to a potential

Industry Impact Weighed As US Supreme Court Refuses Skinny-Label Review

By David Wallace

18 May 2023

Teva has been denied in its attempt to convince the US Supreme Court to re-examine long-running litigation with GSK over skinny-label carve-outs of generic indications. However, the generics firm has vowed to fight on as the case is returned to the district court level, while the wider off-patent industry weighs the impact of the latest decision.

Read the full article here

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