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FDA to Share Rejection Letters Drugmakers Often Keep Secret

By Damian Garde and Sam Hornblower2025-07-10T05:00:00005-04:00

The head of the US Food and Drug Administration said the agency will start publishing the rejection letters that companies until now have mostly kept hidden from investors and the public.

“We had a long set of meetings with our lawyers to determine that we can do this,” FDA Commissioner **Marty Makary** said in an interview with Bloomberg Television’s *Wall Street Week* with **David Westin**.

Dr. Marty Makary, FDA Commissioner on FDA drug transparency
Source: Bloomberg

The agency has historically left it up to drugmakers to disclose when and why their medicines aren’t approved. But companies often give incomplete or misleading accounts of their interactions with regulators, and that can make an application’s deficiencies seem more minor than they really are, Makary said in the interview airing Friday.

“There’s an opportunity for companies to spin the results,” he said. “Now, the decision letters will be public for shareholders and the public to see.”

Investors have long asked the FDA to share its reasons for rejecting drugs, arguing that companies can use the agency’s silence on the matter to mislead the market.

A 2015 FDA study found that manufacturers’ press releases about rejection letters often omitted key information. Companies didn’t issue anything for almost one in five rejections, according to the agency analysis published in the BMJ. When drugmakers did put out a release, fewer than 17% accurately matched the agency’s statements on the safety and efficacy of the drugs.

Scott Gottlieb, who led the FDA during President Donald Trump’s first term, advocated for more openness. He ultimately abandoned the effort after determining that the administrative burden of redacting proprietary information from rejection letters wouldn’t be the best use of agency resources.

Makary said that some drug developers also want the letters to be made public so they can better understand the FDA’s rationale and how to navigate the regulatory process.

“We’re just trying to create a transparent standard so that there can be a level playing field,” he said.

Makary didn’t say when the FDA would begin making its rejection letters public. The effort is part of a “radical transparency” push being spearheaded by Health and Human Services Secretary Robert F. Kennedy Jr.

The interview is airing 6 p.m. in New York on Friday.

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