In the News

Is there “fake news” surrounding FDA approval numbers?

By: Cindy H. Dubin, Senior Editor
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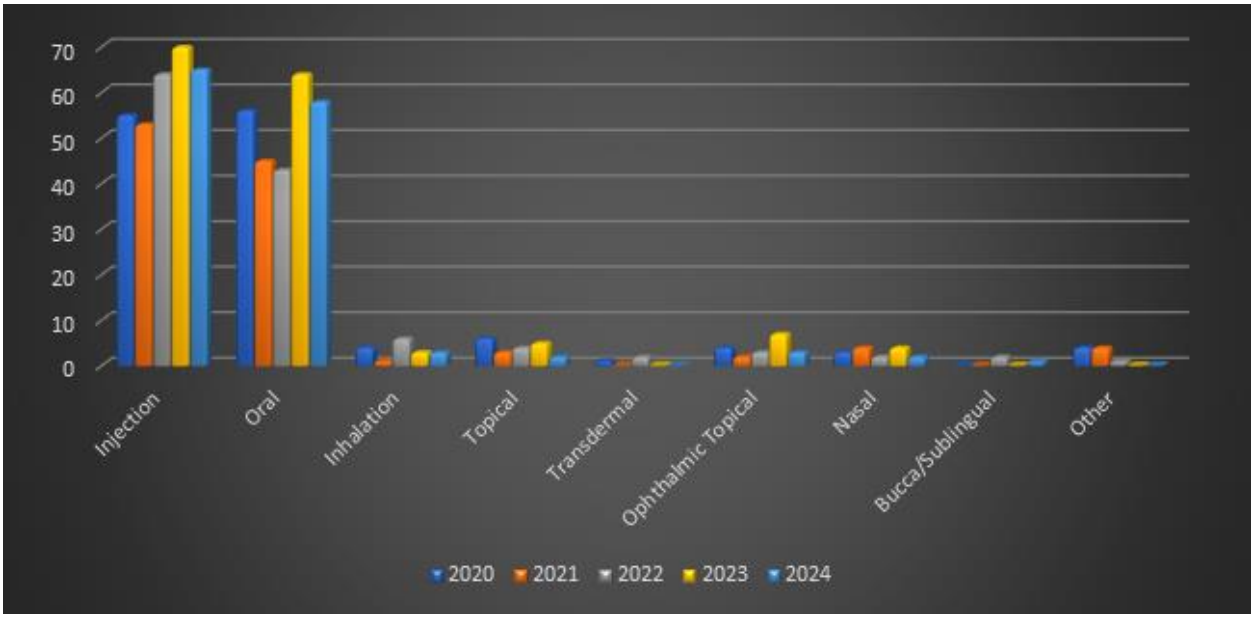
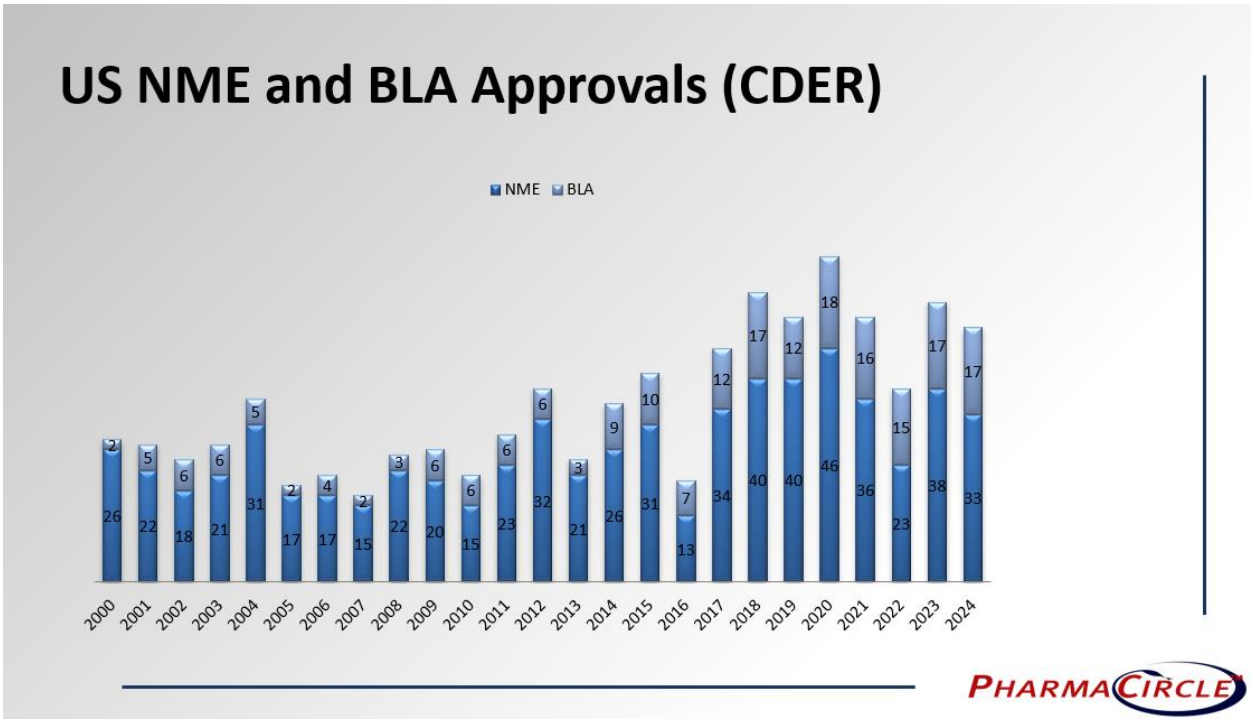
Like you, PharmaCircle editors have been reading the myriad of articles about slow FDA approvals and a non-responsive agency, causing delayed clinical trials. The math being reported is that we are on pace for 38 FDA drug approvals this year, compared to 55 annually in the first Trump administration and 48 annually under the Biden administration. PharmaCircle wanted to know if this is fuzzy math. The number of approvals under each administration is correct, however, the notion that 2025 numbers are dwindling is not true. While it does seem like there was a slight dip in 2024 with NDAs below 100 (**Figures 1 and 2**), as of now, there are already 93 NDAs approved in 2025. This is on trend to be above 100, which is, in fact, in line with the past five years.

Figure 1: US Innovator Approvals 2020-2024



Source: PharmaCircle Pipeline and Products Intelligence

Figure 2: NME Approvals



Source: PharmaCircle 2024 Formulation Report, Part1

“Looking at CDER’s number of novel drug approvals in only a given specific year can be misleading,” an FDA spokesperson tells PharmaCircle exclusively. “We’ve seen fluctuations in approval numbers over the years, sometimes with sharp increases or decreases from just one year to the next. In general, the number of novel drugs CDER approves is dependent upon the number of applications we receive and file, including resubmissions.”

Kyle Sampson, a partner at King & Spalding who focuses on FDA regulatory, compliance and enforcement issues, says there are several reasons why things could slow down, including budgetary cuts and the current government shutdown. However, he says the current administration has indicated that it is concerned about the pace of approvals and is implementing AI tools to enhance regulatory reviews.

“Under Commissioner Makary’s strong leadership, the agency is prioritizing procedures that accelerate drug approvals so Americans can benefit sooner,” says the FDA spokesperson.

As an example, the current administration has rolled out new accelerated approval programs, like the Commissioner’s National Priority Voucher pilot program, which is designed to reduce product application review times for proposed products that address a major national priority or meet a large unmet medical need.

Replimune Group, which is addressing an unmet medical need in advanced melanoma, seemed to have promising clinical trial results for its skin cancer drug RP1. The FDA stated in a Complete Response Letter issued in July 2025, that the single-arm IGNYTE study did not provide “substantial evidence of effectiveness” and its results could not be adequately interpreted.

There is no debating that drug development is risky and costly, and any slowdown in approvals could discourage investment. “Slow approvals also can kill financially strained, early-stage, emerging pharmaceutical companies that are developing innovative products, but do not have unlimited capital,” says Sampson. “The faster these companies can get their products approved and move to commercialization, the greater the likelihood that they will survive. And, obviously, slow approvals impact patients by effectively denying them access to safe and effective treatments.”

He offers life science leaders some key advice:

- Know the reviewers who have your application and the personality and idiosyncrasies of the review division;
- Knowing your target approval date under the Prescription Drug User Fee Act;
- Understand FDA’s internal review timelines for reviewing an application;
- Take opportunities to request meetings with the review division to resolve concerns (choose your battles carefully and preserve good will with reviewers to the extent you can);
- Listen closely to reviewers for indications of concern, doubt, or need for new or different analysis of data and strive not to be surprised when FDA identifies deficiencies with your application;
- Assess deficiencies and determine the cost and time to correct them—and then carefully consider whether to correct those deficiencies or appeal.

“It’s hard for me to say whether, at the end of the year, there will be fewer drug approvals than in previous years, but new initiatives coming online at FDA signal that the agency wants to streamline application reviews and get innovative products to patients quickly,” says Sampson.

About PharmaCircle

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