



# Mass Layoffs at FDA Could Have the Greatest Impact on Products in Development

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## Key Points

- Companies that interact with FDA are likely to find that the layoff of 3,500 employees on April 1, 2025, affects their dealings in a variety of ways.
- The cuts will likely have the greatest impact on products in development, because the agency may not be able to issue as much guidance as it had previously, or provide feedback and updates on applications. Additionally, approval dates are likely to be less predictable.
- The layoffs could also lead to a reduction in inspections, despite FDA's statements to the contrary.

The Department of Health and Human Services (HHS) terminated 3,500 employees at the Food and Drug Administration (FDA) on April 1, 2025. While HHS officials have stated publicly that the reduction in force would not impact medical product and food reviewers or inspectors, it appears likely that FDA's ability to review and approve products nevertheless will be profoundly affected.

The reduction in force eliminated employees and offices in multiple support areas at FDA, including:

- Policy staff who write guidance documents and regulations.
- Project managers who keep industry apprised of the status of application reviews, answer regulatory questions and generally keep agency business running.
- Scientists who test products for adulteration and develop much of the regulatory science underpinning FDA's review standards.
- Communications staff who issue press releases, update FDA's website, and inform consumers about health risks and new product approvals.

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Even before the April 1 layoffs, industry participants had noticed a decline in FDA's responsiveness, especially to nonessential or routine questions. The removal of staff who support the agency's day-to-day operations will likely only aggravate that issue.

The layoffs, combined with a potential redesign or elimination of user fee programs, will result in a paradigm shift for the way industry interacts with FDA.

Below are key changes that regulated industry should anticipate with respect to product review under the new FDA.

## Products in Development

For products that are currently in development — particularly early stage and innovative products — the experience with FDA may be substantially altered.

- **Feedback.** Given the level of staff reduction and attrition, FDA likely will not have the bandwidth to provide much early feedback on drug and device development programs. There are already reports that the Center for Devices and Radiological Health (CDRH) program for sponsor interactions created through the Medical Device User Fee Amendments of 2017 (Q-Sub Program) has been dramatically reduced and meetings converted to written responses only.
- **Pilot and other special programs.** Development programs that are currently reliant on pilot or other special programs described in user fee agreements likewise may need to pivot to a standard development process without additional support from FDA.
- **Information requests.** FDA historically has been willing to send information requests to sponsors to address deficiencies in applications, with the goal of helping them reach approval on the first review cycle. If there is less of that kind of support due to staffing constraints, applicants should not submit applications expecting to be able to correct them during the review process. To conserve agency resources, FDA is more likely to move to address application deficiencies through a (i) complete response letter, (ii) refusal to approve or (iii) not substantially equivalent action.
- **Approval dates.** Approval dates may become less predictable. While user fee programs historically have established a clear set of expectations for when FDA will act on product applications, resource constraints may mean that industry cannot rely on those dates as ironclad. Companies may wish to consider this potential lack of predictability when framing public

communications about prescription drug user fee amendment (PDUFAs) or medical device user fee amendment (MDUFA) dates. Potential changes to user fee programs during upcoming reauthorization cycles are likely to exacerbate this issue.

- **Review updates.** FDA is likely to provide fewer updates about products under review, and it may be harder to get information from reviewers. Sponsor correspondence was previously handled by project management staff, who were eliminated in the layoffs. As such, FDA's medical product reviewers will be responsible for corresponding directly with sponsors' regulatory affairs staff. Given their product review responsibilities, they may not be able to provide frequent or thorough updates on applications under review.
- **Guidance and regulation.** The reduction in force included the majority of policy staff responsible for drafting guidance documents and regulations, and reviewing the complex legal requirements around follow-on or "me too" products filed under Section 505(b)(2) of the Food, Drug, and Cosmetic Act and abbreviated new drug applications. The lack of direction may hinder development, especially for products that rely on FDA guidance, such as new and innovative products or complex generics. Given these changes, we do not anticipate the same regular flow of guidance and regulations from FDA.

## Marketed Products

It is unlikely that the changes discussed above will have the same impact on products already on the market. However, we would anticipate that reviews of efficacy, labeling and manufacturing supplements may be disrupted or less predictable.

In addition, although HHS has said that the layoffs do not impact inspection personnel, media outlets have reported that routine Current Good Manufacturing Practice (CGMP) inspections have become fewer and less frequent. There may also be a reduction in warning letters as a result.

Finally, the staff that responds to citizen petitions has been substantially reduced, likely impacting FDA's responsiveness and the utility of the citizen petition pathway to effect change at the agency.

We will continue to monitor and provide updates as the transformation process at FDA unfolds.

(For more on changes at FDA, see "[FDA at the Start of the Trump Administration: A Cheat Sheet.](#)")

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