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FDA Focuses on Individualized Gene Therapy Development, Issues Draft Guidance on BLA Submission and Postapproval Management for Individualized Human Genome Editing Products

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On October 27, 2026, the Food and Drug Administration (FDA) issued draft guidance on how to submit and manage a Biologics License Application (BLA) for individualized human genome editing (GE) products including multiple product variants. The draft guidance, *Individualized Human Genome Editing Products: Considerations for BLA Submission and Postapproval Management*, is open for public comment until November 27, 2026.

The draft guidance adds to FDA's existing guidance on human GE products by providing recommendations for managing and submitting BLAs and BLA supplements for individualized GE products. Its scope is limited to products intended to prevent, treat or cure monogenic diseases caused by known pathogenic gene variants and where all product variants are designed to achieve the same editing outcome.

A central feature of the draft guidance is FDA's proposed "individualized feature space" (IFS), which describes the allowable limits of variation for a product's GE components within the scope of a single BLA. The guidance lays out how applicants would propose an IFS supported by clinical data paired with explicit *in vitro* safety and activity criteria. The guidance states that in most cases, after approval, new product variants that fall within an established IFS may be added through a BLA supplement based on *in vitro* data without conducting additional clinical studies, relying on the clinical evidence supporting the approved BLA. This applies where the relationship between *in vitro* data and clinical safety and effectiveness is well understood and predictable. Where that relationship is not well understood or predictable

for any specific new product variant, FDA expects clinical data. FDA also recommends that applicants use a postapproval change management protocol (PACMP) to add variants predictably. This framework could reduce duplicative development requirements and allow for quicker access to more therapeutic options for patients.

The guidance is intended to complement other human GE product guidance by offering additional advice and considerations with the goal of supporting the development of individualized therapies and efficient access for patients with rare genetic diseases. It is the latest development in a series of announcements by the agency focused on advancing rare disease drug development, building on the **plausible mechanism** guidance announced earlier this year, the more recent rollout of the **Rare Disease Framework Initiative** to advance "fit for purpose" development and continued focus on cell and gene therapy drug development reflected in the **draft Prescription Drug User Fee Act (PDUFA) VIII commitment lette**r. Rare disease drug development remains an area of strong bipartisan interest on Capitol Hill and is expected to be a topic that comes up as Congress considers PDUFA reauthorization in the coming months.

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