USDA under pressure to liberalize regulation of human gene-therapies and gene-editing, so US doesn't fall further behind other countries

The US Food and Drug Administration's growing comfort with gene editing has sparked a more relaxed regulatory approach to the products.

Gene editing is a concerning subject for the FDA because the products could unknowingly cause heritable genetic modifications that harm patients. At first, the agency set high safety standards for gene editing trials to proceed in the US.

Center for Biologics Evaluation and Research Director Peter Marks admitted that the bar may have been set too high initially for some gene editing products.

"We may adjust the bar a little bit," Marks told the *Pink Sheet* on 16 October. "We would like to recalibrate and for people to know that we're open to consideration and you don't have to go to another regulator."

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The adjustment is not surprising given the continued growth of gene therapy development. CBER has approved 15 products, including several over the last two years, with many more in various development stages.

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Even as the FDA increases its confidence with gene therapy and gene editing, challenges remain, including with product safety.

The FDA wants sponsors to monitor patients for up to 15 years after treatment to ensure long-term patient safety and efficacy.

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