23andMe returns with FDA-approved genetic health tests

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In this Feb. 20 2013 file photo, 23andMe CEO Anne Wojcicki speaks at an announcement for the Breakthrough Prize in Life Sciences at Genentech Hall on UCSF's Mission Bay campus in San Francisco. Google-backed genetic testing company 23andMe on Wednesday, Oct. 21, 2015 said it is reintroducing some health screening tools that federal regulators forced off the market more than two years ago, due to concerns about their accuracy and interpretation by customers. (AP Photo/Jeff Chiu, File)

Genetic testing company 23andMe is reintroducing some health screening tools that federal regulators forced off the market more than two years ago, due to concerns about their accuracy and interpretation by customers.

The Google-backed company said Wednesday it will again offer 35 tests that tell users whether they carry genetic mutations for rare diseases like cystic fibrosis, which can be passed from parents to children.

The relaunch comes as the Silicon Valley company works to mend its relationship with the Food and Drug Administration and medical experts who have criticized the company's direct-to-consumer approach. FDA officials ordered 23andMe to stop selling its health-related tests in 2013, saying they required federal review. The agency signed off on the returning tests earlier this year.

CEO Anne Wojcicki said 23andMe submitted studies to the FDA showing that users can understand genetic test results without the aid of a doctor or health counselor.

"Today we've successfully established a framework for working with the FDA to bring back reports directly to the consumer," Wojcicki said in an interview. "And we'll continue to work to try and bring all of this information back."

The relaunch is a partial victory for the Mountain View, California-based company, but not a total comeback. 23andMe still cannot offer more than 250 risk reports included in its original product, which purported to tell users if they were likely to develop diseases like Alzheimer's and Parkinson's. Those reports and others related to drug reactions remain unavailable in the U.S.

23andMe previously said in February it would resume selling certain

health tests later this year.

More than 1 million people have used the company's saliva-based test kit, a small plastic tube that customers fill with spit and return to the company for processing. About 80 percent of those customers have authorized the company to sell their data to drugmakers and academics for research purposes.

23andMe's current service mainly provides information about family history and ancestry, which is not regulated by the FDA. The company competes with the website Ancestry.com, which offers similar information based on DNA analysis.

As part of the relaunch, 23andMe is highlighting a re-designed website which offers customers new tools to understand their genetic code and compare it to family members. The website also provides links to speak with a genetic counselor about the results.

New customers will pay more for the updated 23andMe experience. The company will charge $199 per person, up from $99.

"We took a lot of the feedback that we'd gotten over the last seven years and then incorporated that with all the FDA feedback into a whole new report format," Wojcicki said. The company plans TV and radio ads to promote the relaunch.

Older 23andMe customers will be gradually transitioned to the new website in coming months.

23andMe launched in 2006 amid a flurry of publicity and celebrity endorsements, promoting its test kit as an affordable way to peek into one's genetic code. But the company's aggressive marketing and questionable science attracted scrutiny from experts.

Since 2013, Wojcicki has hired a number of new executives with experience in the pharmaceutical and medical testing industries.

Wojcicki is divorced from ex-husband Sergey Brin, co-founder of Google. Both Google and Brin invested millions in 23andMe, which is privately held.