US tells 23andMe to halt sales of genetic test

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This image provided 23andMe shows the company's logo. The U.S. Food and Drug Administration is ordering genetic test maker 23andMe Monday, Nov. 25, 2013, to halt sales of its personalized DNA test kits, saying the company has failed to show that the technology is backed by science. (AP Photo/23andMe)

The U.S. Food and Drug Administration is ordering genetic test maker 23andMe to halt sales of its personalized DNA test kits, saying the company has failed to show that the technology is backed by science.

In a warning letter posted online, FDA regulators say the Google-backed company is violating federal law because its products claim to identify health risks for more than 250 diseases and health conditions.

Only medical tests that have been cleared by the FDA are permitted to make such claims.

The letter follows years of back-and-forth between the government and 23andMe, the most visible company among a new field of startups selling personal genetic information. The proliferation of consumer-marketed genetic tests has troubled many public health officials and doctors who worry that the products are built on flimsy science.

For years, 23andMe resisted government regulation, arguing that it simply provides consumers with information, not a medical service. But last year the company appeared to change course, submitting several of the disease-specific tests included in its test kit.

A spokeswoman for the California-based company said 23andMe recognizes "that we have not met the FDA's expectations," for addressing questions about the submission.

"Our relationship with the FDA is extremely important to us and we are committed to fully engaging with them to address their concerns," said Kendra Cassillo in a statement.

The FDA letter suggests that regulators have gone to great lengths to try and work with the company. Regulators even mention "more than 14 face-to-face and teleconference meetings, hundreds of email exchanges, and dozens of written communications."

"However, even after these many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically

validated," its technology, the letter states.

The FDA warning takes issue with a number of claims the company makes for its saliva-based test kit, particularly calling it a "first step in prevention" against diseases like diabetes, heart disease and breast cancer. Regulators worry that false results from the test could cause patients to receive inadequate or inappropriate medical care.

For instance, 23andMe says its test can identify women who carry the BRCA gene mutation that significantly increases the risk of breast and ovarian cancer. But a false result could lead women to undergo unnecessary screening, chemotherapy and surgery.

The test also claims to predict how patients will respond to popular drugs, including the ubiquitous blood thinner warfarin, which is used to prevent blood clots. The FDA warns that an inaccurate reading there could "have significant unreasonable risk of illness, injury, or death to the patient," if they don't receive the appropriate drug dose.

23andMe was co-founded by Anne Wojcicki, who married Google co-founder Sergey Brin in 2007. Google confirmed in September that the two are separated, though Google and Brin have invested millions in the privately held company over the years.

23andMe executives have previously said that they first contacted the FDA in 2007, before launching their product. The agency did not take an interest in the technology until 2010, when it issued letters to several testing companies, stating that their products are considered medical devices and must be approved as safe and effective.

The FDA already regulates a variety of genetic tests administered by health care providers, such as those given to pregnant women to detect cystic fibrosis in a developing fetus. The FDA's concern with 23andMe

appears to center on its commercial approach, which sidesteps doctors and health professionals.

Consumers order the company's product online. When the kit arrives by mail consumers are instructed to spit into a small tube, providing a saliva sample which is sent back to the company for analysis. 23andMe says the customer's DNA is analyzed to determine their likelihood of developing various diseases and responding to various drugs. The test also claims to provide information about ancestral background, though this information is not regulated by the FDA.