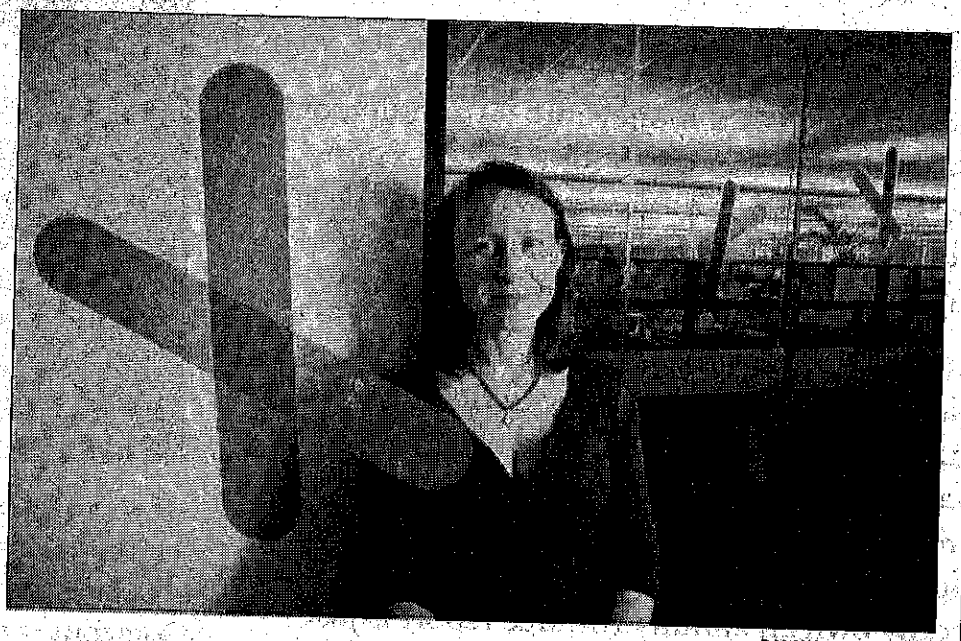

Co-founder and CEO of 23andMe, Anne Wojcicki, seen in a 2011 file photo. DAI SUGANO/BANG FILE

23andMe ordered by FDA to stop selling genetic tests

By STAVE JOHNSON
Bay Area News Group

MOUNTAIN VIEW — In an unusually harsh warning letter, the U.S. Food and Drug Administration has ordered genetic-testing company 23andMe to stop selling its service to consumers because the agency hasn't approved it and fears it could endanger lives.

The letter, which was dated Friday, notes that the regulatory agency has been working with 23andMe since 2009 to help it comply with regulatory requirements regarding the safety and effectiveness of its "Personal Genome Service," which tests people's saliva for genetic indications of 254 disease conditions and other potential health risks.

The agency noted that it has had "more than 14 face-to-face and teleconference meetings, hundreds of email exchanges and dozens of written communications" with 23andMe officials. "However, even after these many interactions with 23andMe, we still do not have any assurance that the firm has analytically or clinically validated the PGS for its intended uses," it added.

Some uses for the company's tests "are particularly concerning," the FDA said, "because of the potential health consequences that could result from false positive or false negative assessments for high-risk indications."

If the test reports a false positive for breast or ovarian cancer, for example, "it could lead a patient to undergo prophylactic surgery, chemoprevention, intensive screening, or other morbidity-inducing actions, while a false negative could result in a failure to recognize an actual risk that may exist," the FDA said.

It demanded that 23andMe "immediately discontinue marketing" the testing service until it gets FDA approval for the product.

Although CEO Ann Wojcicki was not immediately available for comment, 23andMe said in a prepared statement that "our relationship with the FDA is extremely important to us and we are committed to fully engaging with them to address their concerns."

Officials at 23andMe, which was founded in 2006, declined comment on what impact the FDA's action might have on their business and whether the company would be able to continue processing genetic tests from customers.

DNA tests sold directly to consumers have been criticized as having limited value because they typically examine only a small sample of a person's genetic makeup.

In 2010, investigators from the U.S. Government Accountability Office concluded that 23andMe and Navigenics of Foster City were offering information that was "misleading and of little or no practical use." Although both companies defended their products, the agency blasted them for drawing unsupportable conclusions and making health predictions that didn't always jibe with their customers' actual medical conditions.