FDA approves first direct-to-consumer genetic risk tests

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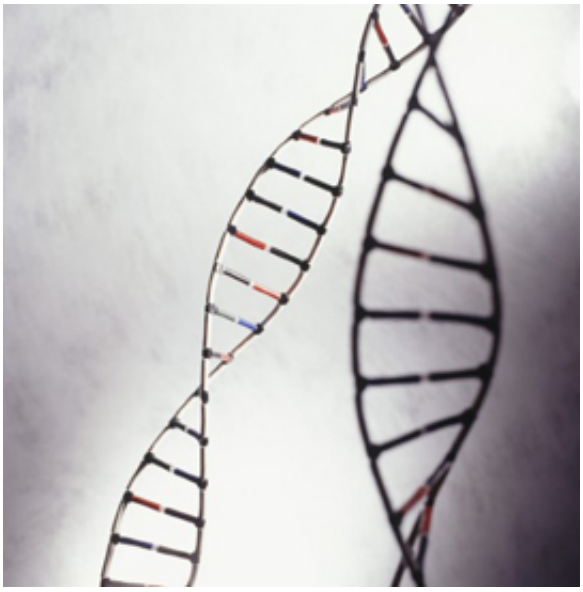

Credit: NIH

(HealthDay)—The U.S. Food and Drug Administration on Thursday approved the first direct-to-consumer genetic health risk tests.

Known as the 23andMe Personal Genome Service Genetic Health Risk tests, they assess a person's inherited risk for 10 diseases and conditions.

"Consumers can now have direct access to certain genetic risk information," said Dr. Jeffrey Shuren, director of the FDA's Center for Devices and Radiological Health. "But it is important that people

understand that genetic risk is just one piece of the bigger puzzle, it does not mean they will or won't ultimately develop a disease."

The tests may be used to "make decisions about lifestyle choices or to inform discussions with a health care professional," the agency said in a news release.

The tests derive DNA from a saliva sample, which is then screened for more than 500,000 genetic variants that are associated with an increased risk for the following diseases or conditions:

- Parkinson's disease;
- Alzheimer's disease (late onset);
- Celiac disease;
- Antitrypsin deficiency (Alpha-1), a disorder that raises the risk of lung and liver disease;
- Primary dystonia (early onset), a movement disorder involving involuntary muscle contractions and other uncontrolled movements;
- Factor XI deficiency, a blood clotting disorder;
- Gaucher disease (type 1), an organ and tissue disorder;
- Glucose-6-Phosphate Dehydrogenase deficiency; a red blood cell condition;
- Hemochromatosis (hereditary), an iron overload disorder;
- Thrombophilia (hereditary); a blood clot disorder.

The agency said it had established "special controls" to clarify its expectations of how well the tests should perform. The FDA said it also had crafted streamlined procedures to make it easier for other makers to develop and submit similar tests for approval.

The agency said in approving the tests, made by 23andMe Inc. in Mountain View, Calif., it analyzed data from peer-reviewed studies that

demonstrated "a link between specific genetic variants and each of the 10 health conditions."

The FDA did warn that the tests could yield false-positive results, indicating incorrectly that a person has a certain genetic variant that would increase risk of a particular disease or condition. Test results should not be used to diagnose or treat a specific illness, the agency added.

More information: To learn more about this approval, visit the FDA.