FDA orders 23andMe to stop marketing DNA test kit

The Food and Drug Administration is demanding that 23andMe immediately cease all marketing for its main DNA service until it receives marketing clearance from the agency.

In a letter posted on their website Monday, the FDA said that 23andMe had failed to provide adequate evidence that its Personal Genome Service provided accurate results. “F.D.A. is concerned about the public health consequences of inaccurate results from the P.G.S. device,” the agency said in its letter. “The main purpose of compliance with F.D.A.’s regulatory requirements is to ensure the tests work.”

23andMe is perhaps the best known of the personal genome testing companies. The company has been at the center of controversy in recent months, as its service has raised some ethical questions about regulating genetic information. Its service, which has been used by about half a million people, informs consumers about their genetic predisposition to certain diseases.

Whether such tests require FDA approval and whether doctors must be involved in ordering such tests have been the subject of much debate. 23andMe has long held that consumers are entitled to the information on their own DNA, though it has also been talking to the FDA about how its tests could receive regulatory approval.

Read the full, original story here: F.D.A. Demands a Halt to a DNA Test Kit’s Marketing