

GENETICS, NOTEWORTHY

FINALLY! 23 AND THE FDA WARNING

28.11.2013

Quite some time passed already since my last post (to be exact, [more than 5 years](#)) but now there are [good news](#). The FDA issued a [warning letter](#) on the 22nd

... The Food and Drug Administration (FDA) is sending you this letter because you are marketing the 23andMe Saliva Collection Kit and Personal Genome Service (PGS) without marketing clearance or approval in violation of the Federal Food, Drug and Cosmetic Act (the FD&C Act) ... 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 ... Therefore, 23andMe must immediately discontinue marketing the PGS until such time as it receives FDA marketing authorization for the device ...

The response is quite [flimsy](#). Yes, there may be negative side effects of genetic testing and of course tests need to be validated first. [Slate may be correct](#) that the FDA's battle with 23andMe won't mean anything in the long run but now at least, we are set back to science, yea, yea.

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