FDA Issues Draft Guidance Affecting Personalized Biologics

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On July 14, the FDA issued a new draft guidance concerning in vitro companion diagnostic devices ("IVD companion diagnostic devices"). As explained in its press release, such IVD companion diagnostic devices are already in use to identify patients that are most likely to benefit from certain therapeutic products, such as some monoclonal antibodies.

The draft guidance focuses on an integrated approach to approval of therapeutic products and their IVD companion diagnostics. Much of the guidance addresses simultaneous review of a new biologic (or drug) and a companion test, particularly where safe and effective use of the treatment depends on the companion test. The guidance is clear evidence that the FDA appreciates the importance that personalized medicine will assume in the coming years.