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No comments: Post a Comment Share About Me Hello! This blog is owned and operated by me, Sue Kim. I love to write about all of my interests, including my experiences as a Korean adoptee, living in the U.S. and of course, Universal Studios. My hope is that what I have to say will not only provide you with some amusement but also prove to be an intriguing read!FDA Proposes End to Ban on Industry-Developed Genetic Tests Following a six-year process of developing guidelines for the use of DNA information in the agency's regulated product testing, the U.S. Food and Drug Administration announced today that it is proposing to withdraw its 2008 guidance on the use of personal genetic information in regulated products. The guidance, which applies to all FDA-regulated product categories, was a 2015 update of its guidance on "Genetic Information in Food Labeling." In accordance with 21st Century Cures Act provisions, the agency's proposed withdrawal focuses on consumer-facing genetic tests. "To ensure the continued safety of the nation's products and that the public receives appropriate and truthful information, the Agency is proposing to withdraw the 2008 guidance regarding the use of genetic information in the labeling of foods and dietary supplements," said FDA Acting Commissioner Ned Sharpless in a statement. "This action is in accordance with legislative requirements and reflects consumer preferences today for better information on the benefits and risks of a product. We are proposing this change of course because we must provide consumers and retailers with a new, streamlined approach to the regulatory oversight of genetic labeling." In 2008, the agency established guidance that addressed the regulation of consumer-facing genetic tests, including those that were intended to be used to determine whether a consumer has a specific illness. The guidance emphasized the need for genetic tests to be accurate, fair, non-misleading, properly vetted and without clinically unsubstantiated claims. It also stressed that consumers have the right to access genetic information and that it should be associated with a product or a family history. Following the passage of the 2016 Cures Act, however, the agency's goal was to focus on the risk-benefit assessment of the Food, Drug and Cosmetic Act (FD&C Act) as it relates to consumer-facing genetic tests. The new guidance, which would apply only to FDA-regulated products, would not address genetic tests used in the f30f4ceada