

Advisory Warning on Vision Test App Technology

Ensuring the health, safety and well-being of New Mexicans is an urgent high priority for the Board of Optometry. It is for this reason, this office is alerting the public to health, safety and device approval concerns identified by the U.S. Food and Drug Administration (FDA) involving Opternative, a company that markets a vision test via the Internet, and all companies it works with to further the use of its product.

The FDA issued a warning letter to Opternative in October 2017, stating that Opternative should *"immediately cease activities that result in the misbranding or adulteration of the On-Line Opternative [device], such as the commercial distribution of the device through your online website."* The FDA has found that the Opternative device did not complete approval requirements needed to assure safety and effectiveness.

Opternative's service is currently offered directly to New Mexicans at this time, and this office has been made aware that the company maintains arrangements with at least one large Internet-based mass retailer of contact lenses operating nationwide to offer contact lens prescriptions not connected to a comprehensive eye examination by an eye doctor, a recognized standard of care, as well. Accordingly, whenever and wherever New Mexicans should encounter advertised product claims connected to vision test apps, this office urges the public to proceed with appropriate caution, to remain mindful of the importance of safeguarding eye health and vision and, as needed, to seek further relevant and reliable health care information.

This advisory will be held in force until our state receives notification that Opternative, its partners, agents and collaborators, have met and will adhere to all applicable health, safety and medical device approval requirements and laws. For more information, please contact this office directly or the FDA (www.FDA.gov).

New Mexico Optometry Board website: <http://www.rld.state.nm.us/boards/optometry.aspx>

FDA Warning Letter can be found here:

<https://www.fda.gov/iceci/enforcementactions/warningletters/2017/ucm600029.htm>