California Optometric Association
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May 9, 2018

The Honorable Xavier Becerra
California Attorney General
California Department of Justice
P.O. Box 944255
Sacramento, CA 94244-2550

Re: Request for Investigation:
Opternative, Inc./1-800-CONTACTS

Dear Attorney General Becerra,

This letter is written on behalf of the California Optometric Association and its nearly 4000 members licensed to practice optometry in California.

Enclosed is a "**warning letter**" dated October 30, 2017 from the U.S. Food and Drug Administration to Opternative, Inc. in connection with its On-Line Opternative Eye Examination Mobile Medical App Device (Device). The letter states, among other things: "The United States Food and Drug Administration (FDA) has learned that your firm is marketing the On-Line Opternative Eye Examination Mobile Medical App device in the United States without marketing clearance or approval, in violation of the Federal Food, Drug, and Cosmetic Act (the Act)." The warning letter was publicly released in March of 2018.

The warning letter states during a June 15, 2016, meeting with the FDA, Opternative Inc., was directly told by both the FDA Office of Compliance and the FDA Office of Device Evaluation the Device required a "…premarket submission in order to allow the (FDA) to evaluation its safety and effectiveness." Yet, it appears Opternative never complied with this directive, based on (1) the fact the FDA sent a formal warning letter to Opternative sixteen months after the June 2016 meeting, and (2) Opternative currently does not appear to have a pre-market submission pending before FDA.

In a public statement made on March 21, 2018 – shortly after the public release of the warning letter but nearly five months after the warning letter was received by Opternative, Opternative claims it "responded" to the FDA, and "continue(s) to communicate with the FDA on a regular basis," and it is "work(ing) through the regulatory medical device clearance process with our outside experts." Notably, Opternative did <u>not</u> assert it has an application for pre-market approval (PMA) pending before the FDA, which is the remedy the FDA required of Opternative in order for Opternative to cure its violation of federal law.

The Device was marketed, and continues to be marketed, to the public in 33 states by Opternative, Inc. with the active cooperation of 1-800-CONTACTS (see enclosed material and joint marketing statements). Public health is therefore potentially threatened by a medical device actively marketed to the public despite not having gone through the required review and approval processes demanded by the FDA.

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The two key consumer protection statutes are the Unfair Competition Law (UCL) [Cal. Bus. & Prof. Code § 17200] and the Consumers Legal Remedies Act (CLRA) [Cal. Civ. Code § 1750]. The UCL extends to "unlawful, unfair, or fraudulent business acts or practices and unfair, deceptive, untrue, or misleading advertising." Section 17200 establishes four potential theories of liability: (1) unlawful business acts or practices; (2) unfair business acts or practices; (3) fraudulent business acts or practices; and (4) unfair, deceptive, untrue, or misleading advertising. The CLRA is "liberally construed and applied to promote its underlying purposes, which are to protect consumers against unfair and deceptive business practices and to provide efficient and economical procedures to secure such protection." [Cal. Civ. Code, § 1760]. We respectfully submit the joint marketing efforts of the unapproved Device by Opternative, Inc. and 1-800-CONTACTS constitute misleading and deceptive acts in the conduct of trade or commerce and the consuming public needs to be protected. We ask your office to investigate.

Several courts found reason for misrepresentations about effectiveness to be a predicate act for a Racketeer Influenced and Corrupt Organizations (RICO) action and recovery. For example, one court ruled liability can be based on "plainly foreseeable" injuries to the public (*In re Neurontin Marketing & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013). In another case, involving charges of RICO violations against a pharmaceutical manufacturer, a court found the alleged overpayment by payers for a drug due to illegal or deceptive marketing practices was a sufficiently concrete injury to be actionable under RICO (*In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015) at 640-641). Similar to the *In re Neurontin Marketing & Sales Practices Litig*. case, the court in the *Avandia* case concluded the alleged harm was directly related to the misrepresentations. Relying on *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008), the court explained the defendant in the case, GlaxoSmithKline, was aware payers would cover the costs of its drugs and, thus, the alleged injury was a "foreseeable and natural consequence of [the] scheme." (*In re Avandia Marketing, Sales Practices & Product Liability Litigation*, 804 F.3d 633 (3d Cir. 2015) at 645).

Therefore, the California Optometric Association respectfully requests your office take prompt action to protect the health and safety of 39.5 million residents by investigating whether the joint enterprise between Opternative, Inc. and 1-800-CONTACTS to market the unapproved Device is a violation of California's Unfair Competition Law. If warranted, we call for your office to take prompt enforcement action against Opternative, Inc and 1-800-CONTACTS.

Sincerely,

Ranjeet S. Bajwa, OD, FAAO, Dipl ABO
President