



March 16, 2021

Rebecca Kelly Slaughter  
Acting Chair  
Federal Trade Commission  
600 Pennsylvania Avenue NW  
Suite CC-5610 (Annex B)  
Washington, D.C. 20580

Janet Woodcock, M.D.  
Acting Commissioner of Food and Drugs  
Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20852

Dear Acting Chair Slaughter and Acting Commissioner Woodcock,

The American Optometric Association (AOA) is a leading authority on quality eye care and an advocate for our nation's health and patient safety issues, representing approximately 33,000 doctors of optometry and optometry students. Doctors of optometry are eye and vision care professionals who diagnose and treat diseases and conditions of the eye, such as glaucoma, diabetic retinopathy, macular degeneration, cataract, refractive error, oculomotor dysfunction, and strabismus, among others. A central mission of the AOA is to serve as a resource to the public for reliable and current information related to eye care, health care policy, and patient safety.

We are writing during Patient Safety Awareness Week to notify the FTC and FDA about a company of concern to our organization and our members called VisionFocus<sup>1</sup> that we believe may be marketing and selling a regulated medical device without a 510(k) submission or premarket approval (PMA) from the FDA. Additionally, the claims made by VisionFocus about its device may be violating certain state laws.

VisionFocus sells “the first adjustable eyeglasses” that it claims will “adjust your focal length from -6 to + 3,” referring to the lens diopters, the unit used to measure the correction of the lens the eye requires to see clearly. As you know, any domestic or foreign establishment involved in the production, importation, or initial distribution of reading glasses to be marketed in the United States is required to register with the FDA and to renew that registration annually.<sup>2</sup> We were not able to locate the device on any of the FDA’s searchable Device Approvals, Denials and Clearances databases.<sup>3</sup> Therefore, we are writing to confirm that this device has been registered/approved for sale to patients. Additionally, many state regulations of over-the-counter (OTC) reading glasses make sales of the VisionFocus product illegal in these states. For example, in New York, reading glasses are not permitted to exceed 2.75 diopters, and in Rhode Island, OTC sales are limited to magnifications not exceeding 2.5 diopters.<sup>4,5</sup> New York also requires that a

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<sup>1</sup> <https://getvisionfocus.com/>

<sup>2</sup> <https://www.thevisioncouncil.org/sites/default/files/members/VCSRRegulationsManual62011.pdf>

<sup>3</sup> <https://www.fda.gov/medical-devices/products-and-medical-procedures/device-approvals-denials-and-clearances>

<sup>4</sup> <http://www.op.nysed.gov/prof/od/article144.htm>

<sup>5</sup> <https://law.justia.com/codes/rhode-island/2009/title-5/chapter-5-35-2/5-35-2-5/>

seller of “ready-to-wear” glasses display the following language in any advertising and on each pair of glasses or in plain view in the area of sale: “Attention; ready-to-wear non-prescription glasses are not intended to replace prescribed corrective lenses or examinations by an eye care professional. Continuous eye check-ups are necessary to determine your eye health status and vision needs.”<sup>6</sup> Rhode Island, Minnesota, and Massachusetts have similar point-of-sale or area-of-sale language requirements; VisionFocus does not appear to display any of these required disclaimers anywhere on its website or at the point of sale online.

We are concerned by the vision health claims that VisionFocus has made about this seemingly unapproved medical device. We are hopeful that the Commission and Administration will evaluate the potential breaches of federal and state policies that are in place to protect patients from harm.

Thank you for your attention to these concerns. Please contact AOA’s Associate Director of Regulatory Policy, Emily Dalgo, at [edalgo@aoa.org](mailto:edalgo@aoa.org) with any questions.

Sincerely,

A handwritten signature in black ink that reads "William T. Reynolds O.D." The signature is written in a cursive style with a clear "O.D." at the end.

Bill Reynolds, O.D.  
President, American Optometric Association

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<sup>6</sup> <http://www.op.nysed.gov/prof/od/article144.htm>