



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

OCT - 7 1997

WARNING LETTER

VIA FEDERAL EXPRESS

James M. Callahan  
President  
Vistakon, Incorporated  
Johnson & Johnson Vision Products, Inc.  
4500 Salisbury Road Suite 300  
Jacksonville, Florida 32216

Dear Mr. Callahan:

The Center for Devices and Radiological Health of the Food and Drug Administration (FDA) has reviewed both a tape of a television broadcast advertisement and a magazine advertisement which have resulted in the misbranding and adulteration of Johnson & Johnson's Acuvue® Contact Lenses with UV-Blocker, manufactured and distributed by Vistakon, Incorporated (Vistakon), a division of Johnson and Johnson. The lenses are devices within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act ( the Act). Acuvue Extended Wear Contact Lenses were approved as restricted devices within the meaning of section 520(e) of the Act and Acuvue Daily Wear Contact Lenses were cleared through the premarket notification submission process established in section 510(k) of the Act.

The print ad, which appears in the August 18, 1997 issue of Time magazine and the October issue of Health magazine, shows a man and a woman half inside and half outside a room. The picture, captioned "Open your eyes to the UV around you," shows the couple without any glasses, sunglasses or goggles. The combination of this picture and the accompanying language implies that wearing the Acuvue UV-absorbing lens outside offers as much protection as one would naturally have indoors. Additionally, the question in the text of the ad "So, why would you wear anything else?" creates an impression that use of Acuvue lenses with UV absorber negates the need for other more traditional forms of UV protection, i.e., sunglasses, UV coated glasses, etc. This is misleading and changes the intended use of both the Daily and Extended Wear Contact Lenses with UV-Blocker by implying that these contact lenses provide full ocular protection in environments where consumers are exposed to ultraviolet radiation. Because these lenses offer protection for a limited area of the eye, FDA required that you include in all of the labeling and advertising for

these products a warning statement informing readers that UV-absorbing contact lens are not a substitute for UV-absorbing eyewear such as UV-absorbing goggles or sunglasses and a note stating that the effectiveness of wearing UV-blocking contact lenses in preventing or reducing the incidence of ocular disorders has not been established at this time.

Although Johnson & Johnson has included the required statements in small print in its print ad and flashes an abbreviated version of it in its television ads, the presence of the language does not balance or counteract the overall message of the advertisements, i.e., that Acuvue contact lenses with UV-blocker offer full ocular protection in environments where protection of the eyes from ultraviolet radiation may be necessary. This is misleading.

In its television advertisement (aired on the Washington, DC NBC affiliate on the morning of September 11, 1997) Johnson & Johnson represents its Acuvue UV-absorbing contact lens as providing full ocular protection from indoor fluorescent lights, incandescent lights and sunlight. At the end of the commercial, the actor inserts the lens, walks outside, squints and acts as if he is expecting a problem from the sun, and then proceeds to the table without an apparent problem and asks, " So why would you wear anything else?" In addition to objecting, as described above, to these representations about the extent of the protection provided by your product, we do not believe that a hazard caused by indoor lighting has been established.

Section 502(q) of the Act provides that a restricted device is misbranded if its advertising is false and misleading in any particular. Section 502(r) provides that a restricted device is misbranded unless the manufacturer, packer or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer or distributor with respect to that device a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

Your advertisements have misbranded the Acuvue Extended Wear Contact Lenses within the meanings of both of these sections, because your representations failed to clearly inform the reader that Acuvue UV-absorbing contact lenses are not a substitute for UV-absorbing eyewear such as UV-absorbing goggles or sunglasses. Your ads have created the misleading impression that these contact lens can substitute for other UV-absorbing eyewear and that indoor UV sources create a hazard of such magnitude that UV-absorbing lenses are necessary and that your lenses provide the requisite protection. Additionally, your advertisements, print and broadcast, fail to include a list of the relevant contraindications associated with the use of Acuvue Extended Wear Contact Lenses.

FDA's regulations at 21 CFR 801.4 provide that the term "intended uses" refers to the objective intent of the persons legally responsible for the labeling of the device. That intent may be shown by labeling claims or advertising matter or oral or written statements by such persons or their representatives. Making claims or representations, implied or express, that wearing your company's lenses makes it unnecessary to wear other UV-absorbing eyewear or other protection has changed the intended use for your device, as has the implied claim that you provide full ocular protection from the entire UV spectrum.

Therefore, because your advertisements have represented that Acuvue UV absorbing contact lenses, both Daily Wear and Extended Wear, provide full protection to the eye in environments where protection from UV radiation may be warranted, Acuvue Daily Wear Contact Lenses with UV-Blocker are misbranded within the meaning of section 502(o) of the Act in that a notice or other information respecting the modification of the intended use of the device was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii) and the device was not found substantially equivalent to a predicate device. Further, Acuvue Extended Wear Contact Lenses with UV-blocker are misbranded within the meaning of section 502(o) of the Act in that there was a failure to comply with the requirements of section 515 of the act in that Vistakon failed to file a premarket approval application (PMA) supplement as required by 21 CFR 814.39.

Acuvue UV-absorbing Extended Wear and Daily Wear Lenses are adulterated within the meaning of section 502(f)(1)(B) of the Act in that they are Class III devices within the meaning of section 513(f) of the Act, and do not have an approved PMA in effect pursuant to section 515(a), or an approved application for an investigational device exemption under section 520(g).

Additionally, the print ad for the lenses makes a 95% blockage claim for UVB but fails to inform the reader that UVA blockage is 70%. We believe it is important that you include this information because the overall message in your ads is one of general UV protection.

This letter is not intended to be an all-inclusive list of deficiencies associated with the Acuvue lenses. It is your responsibility to ensure adherence to each requirement of the Act and the Federal regulations. The specific violations discussed in this letter may represent practices used in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to correct these deviations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizing your product

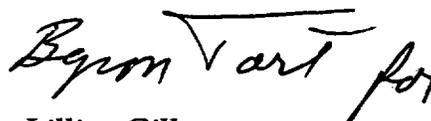
inventory, obtaining a court injunction against further marketing of the product and assessing civil money penalties.

Please notify this office in writing within 15 working days of your receipt of this letter of the specific steps you have taken to correct the cited violations. Your response should include steps being taken to address misleading information currently in the marketplace as a result of both your television and print advertising campaigns and actions to prevent similar violations in the future, including such violations as may be posed by advertising materials that are now pending publication. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Send your response to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland, 20850.

A copy of this letter is being sent to FDA's Florida District Office. Please send a copy of your response to the District Director, Food and Drug Administration (HFR-SE240), 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida, 32809.

Sincerely yours,

A handwritten signature in cursive script that reads "Lillian Gill" with a checkmark-like flourish at the end.

Lillian Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health