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APR 23 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850WARNING LETTERVIA FACSIMILE  
VIA FEDERAL EXPRESS

William M. Carpenter  
Chairman and Chief Executive Officer  
Bausch & Lomb, Incorporated  
1400 North Goodman Street  
Rochester, New York 14692-0450

Dear Mr. Carpenter:

The Promotion and Advertising Policy Staff of the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) has reviewed some promotional material issued by Bausch & Lomb, Inc. (Bausch & Lomb) pertaining to the company's PureVision™ contact lenses. The lenses are devices within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). As described below, these promotional materials have misbranded and adulterated the company's PureVision™ lenses within the meaning of several sections of the Act.

Representations to which FDA objects include implied and express claims that wearing PureVision™ lenses will improve ocular health, that the lenses are in a category called "continuous wear" lenses that is different from the "extended wear" category of which they are a part and that "continuous wear" lenses are superior to "extended wear" lenses because of their design. Additionally, Bausch & Lomb has referred as support for its promotional claims to studies that were not submitted to FDA for review. Bausch & Lomb has created the misleading impression that PureVision™ lenses are a superior form of extended wear lenses and has made claims for which the company has not submitted required data to FDA.

A Bausch & Lomb "fact sheet" obtained at the Vision East meeting held in New York City the week of March 15, 1999 says that the PureVision™ lens is a "continuous wear" lens that is to be worn on a monthly replacement schedule. The sheet also says that "the distinction between a continuous wear product and an extended wear product is that the material of a continuous wear product is designed specifically for longer wearing times and for overnight wear, whereas extended wear products are not designed specifically for this end goal." Your promotional brochure (LMP 1939, SL 2334, printed February 1999), also obtained at the Vision East meeting, and an ad that appeared in the March 1999 issue of "Contact Lens Spectrum," also refer to "continuous wear" of your company's PureVision™ lens.

The statement in the fact sheet is false and misleading because the PureVision™ lenses are considered extended wear lenses and Bausch & Lomb has provided no evidence that their design or construction is superior to that of other extended wear lenses currently in the marketplace. The creation of a “continuous wear” category for contact lenses is inappropriate since it implies that your lenses have an intended use that is different from that of other extended wear contact lenses. While the PureVision™ lens has received CE Mark approval to be marketed “for 30 day continuous wear” in Europe, we object to your referencing this approval in promotional or other materials distributed in the United States because of the 30 day period and the use of the term “continuous wear.”

Use of this term, or any other that implies that PureVision™ lenses are in a category of extended wear lenses different from that of other extended wear lenses may create the impression that your product’s approved indication for use in this country is different from its actual approved indication or from that of the approved indications of other extended wear lenses. The statement of the intended use in your PMA 980006 is as follows: “The Bausch & Lomb ® PureVision™ (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear or extended wear from 1 to 7 days between removals, for cleaning and disinfection or disposal of the lens, as recommended by the eyecare practitioner. . .” [Emphasis added.] Additionally consumers may, based on a reference to the European approval, be encouraged to extend the wearing of their lenses beyond the 7 day period.

Thus, Bausch & Lomb has made statements and other representations related to safety and effectiveness for which the company has not submitted a PMA supplement as required by the agency’s regulations at 21 CFR 814.39. That section requires that after FDA approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety and effectiveness of the device for which the applicant has an approved PMA, unless the change is one for which FDA has provided for an alternative submission. The kinds of changes that require a supplement include, but are not limited to, new indications for use of the device, changes in effectiveness, and labeling changes.

In addition, the promotional brochure makes numerous broad claims regarding the safety and comfort of the lenses and claims that the characteristics of the lens have a significant positive impact on the overall health of the eye.

The page titled “Clinically Confirmed:” claims “a new level of ocular health.” This statement appears to be based on data that Bausch & Lomb provided in its PMA to demonstrate that use of PureVision™ lenses result in overnight corneal swelling comparable to that experienced by persons with no contact lenses. While a straightforward statement about the comparative corneal swelling data may be included in your promotional materials, the agency objects to your conclusion that this results in a “new level of ocular health” because you have not submitted data to support the conclusion. While comparatively greater oxygen permeability may theoretically provide some health benefit, the safety endpoints of your PMA data set did not show any

statistically significant benefit over the control lens which was a currently approved extended wear lens marketed by another firm.

The “Clinically Confirmed” page also includes the claim a “significantly lower level of hypoxia-related effects compared to a conventional EW hydrogel lens” and makes reference to a four-month clinical investigation. The two data sets reported in your Premarket Approval Application (PMA) were for studies of 12 months and six months, and so the claim is based on data not submitted in the PMA.

In addition, the page, “A Precise Balance of Materials” makes the claim that “a high percentage of “bound water” results in minimum dehydration.” The PMA does not include data to support this claim.

We also object to the statement on the “Surface and Design” page that “Continuous wear has never looked healthier” because it makes a claim for “continuous wear,” as discussed above, and implies that use of PureVision™ lenses will improve the overall health of the eye and reduce the risk of any adverse events that are associated with the use of extended wear contact lenses. Bausch & Lomb has provided no evidence to the agency to support these claims.

The same brochure makes a variety of comparative preference claims. One page titled “Confirmed by patients: A new level of comfort and convenience” compares comfort, eye redness, lens dryness and visual acuity, lens handling, ease of insertion/removal and overall preference as reported in a one year clinical investigation of your device. We presume this reference is to your PMA data. However, the patient assessment data reported in the PMA do not appear to support the comparative preference claims reported in the brochure. The conclusion drawn from the studies published in the summary of safety and effectiveness for the device was “overall, the clinical performance of the test lens ... was comparable to that of the control lens.”

Thus, the lenses are misbranded within the meaning of section 502(a) of the Act because of the false and misleading claims discussed above and within the meaning of section 502(o) of the Act because Bausch & Lomb has not submitted to FDA information or a notice respecting the device as required by section 510(k)(2) of the Act. As noted above, the agency’s regulations at 21 CFR 814.39 require that, after FDA approval of a device, applicants submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device. Many of the claims that you have made require the submission to FDA of further data.

The Bausch & Lomb lens is adulterated because it is a class III device for which there is no approved premarket approval application as required by section 515(a) of the Act and no investigational device exemption for the claims as required by section 520(g) of the Act. Each claim that the company makes for the product must be supported by an approved PMA, so that, while the product is the subject of an approved PMA, the unapproved claims make the product an adulterated class III device.

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

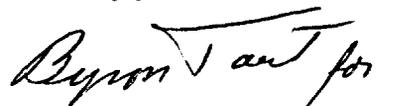
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to address any misleading information currently in the marketplace and to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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

A copy of this letter is being sent to FDA's New York District Office. Please send a copy of your response to the District Director, Food and Drug Administration, 850 3<sup>rd</sup> Ave., Brooklyn, New York, 11232-1593.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian Gill", with a large flourish at the end.

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