



g1762a

SEP 21 2001

WARNING LETTERFood and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850SENT VIA FACSIMILE AND
FEDERAL EXPRESSFred Hassan
Chief Executive Officer
Pharmacia & Upjohn
100 Route 206 North
Peapack, New Jersey 07977

Dear Mr. Hassan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed some of Pharmacia & Upjohn's (Pharmacia's) promotional material for the CeeOn® Edge Foldable Lens (CeeOn® Edge). We reviewed brochures titled, "Introducing CeeOn Edge," "Giving You An Edge On The Competition," and your web sites, www.ophtalmology.pnu.com and www.just-say-no-to-pco.com. Throughout your promotional materials and web sites, Pharmacia asserts that the CeeOn® Edge lens provides protection against posterior capsule opacification (PCO). This claim is not a part of the intended use for the CeeOn® Edge lens, which is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The CeeOn® Edge lens was approved "for primary implantation for the visual correction of aphakia in persons 60 years of age or older in whom a cataractous lens has been removed by phacoemulsification. The lens is intended to be placed in the capsular bag."

Although the prevention of PCO is not encompassed by the intended use of the CeeOn® Edge lens, the brochures cited above contain the following "reduction in PCO" claims.

"It Gives You An Edge Against PCO"

"The next-generation silicone IOL specifically designed to prevent PCO"

"Reduces the incidence of PCO compared with published PCO rates of other lens"

"Get an Edge on PCO"

"Posterior capsule opacification (PCO) is minimized by the square-edge design--90° edge inhibits the migration of lens epithelial cells (LEC)."

It is our understanding that during the PMA review process, Pharmacia sought to add a claim of "reduced incidences of PCO" as part of the approved labeling for the lens. CDRH's Office of Device Evaluation informed Pharmacia that they could report the Nd:YAG rate, but would need additional supporting data to include a claim of reduction in the incidence of PCO. Pharmacia did not provide the data and therefore the dissemination of promotional materials containing such PCO reduction claims is inappropriate.

On the cover of the "Giving You An Edge On The Competition" brochure there is a caption that reads, "CeeOn EDGE versus Allergan S140." The brochure's title and caption suggest that the selection of the CeeOn® Edge instead of Allergan's S140 lens is a superior choice. Within the brochure Pharmacia presents information regarding the Allergan S140 lens and the CeeOn® Edge lens. Although in most instances there are no explicit claims of superiority, the mere presentations of each lens' specifications constitute implied superiority claims. On page three of this brochure you state the following. "No square edge to inhibit PCO." As stated earlier, Pharmacia was informed that, if the company wanted to make claims regarding PCO, data supporting such claims should be submitted for review. Pharmacia elected not to provide such data. Therefore, it is improper to make reduction in PCO claims.

Your description of Allergan's S140 lens as one that has "no square edge to inhibit PCO" misrepresents both the CeeOn® Edge lens and Allergan's S140 lens. Comparative claims in general are only appropriate if there are data resulting from head-to-head comparative studies. As noted above, Pharmacia has not demonstrated that the square edge design inhibits PCO. Nor has Pharmacia demonstrated that its lenses inhibit PCO more than Allergan's S140 lenses do. Therefore, comparative claims based on the CeeOn® Edge lens' design or based on relative inhibition of PCO lack merit.

Claims regarding the reduction in PCO are also found on Pharmacia's web site. The web site contains several abstracts that are reached through links provided at www.ophtalmology.pnu.com/healthcare/meeting/vienna/m.html. One such abstract is titled, "The Pharmacia & Upjohn CeeOn Edge. Early clinical results of barrier edge." This abstract contains portions of a presentation detailing the performance of the CeeOn® Edge in the "U.S. phase III study of the CeeOn Edge model 911." Dr. Colvard, a presenter, stated he could determine whether the CeeOn® Edge had been implanted in patients because their posterior capsules were "crystal clear." We are aware that the abstracts found on your web sites represent presentations that took place abroad. As the claims made in these presentations do not reflect the approved use of your device their availability domestically is also inappropriate. Discussions related to the international use of your device should be presented on a separate web page under an international icon so as not to confuse or mislead your domestic audience.

It is noted that these abstracts can also be reached through the following URL, www.just-say-no-to-pco.com. Pharmacia's creation of a web site address that describes an unapproved use provides another instance of your dissemination of misleading promotional material.

FDA's regulations at 21 CFR 801.4 provide that the intended use of a device refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by circumstances surrounding the distribution of the article. This objective intent may be shown by, for example, labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

Your promotion of the CeeOn® Edge lens as an intraocular lens that provides a reduction in the incidence of PCO misbrands and adulterates the CeeOn® Edge lens. The CeeOn® Edge lens is misbranded within the meaning of section 502(o) because no notice or other information respecting the device was submitted as required by section 510(k) of the Act. The lens is further misbranded within the meaning of section 502(f)(1) because it does not contain adequate instructions for use and does not provide the information required by 21 CFR 801.109(d) to appear in prescription device labeling. All promotional labeling for a prescription device must contain a brief statement of its intended use and relevant warnings, precautions, side effects, and contraindications (risk information). Although your materials contain some of the risk information, one of the relevant side effects that you failed to include is PCO.

The promotion of your lens as one that provides protection against PCO constitutes a major change or modification of its intended use. A major change or modification in the intended use requires the submission of premarket notification, as provided in the agency's regulations at 21 CFR 807.81(a)(3)(ii). The device is further misbranded as provided by section 21 CFR 801.6, which applies to misleading representations in labeling with respect to other devices or other FDA-regulated products.

The CeeOn® Edge lens is adulterated within the meaning of section 501(f)(1)(B) because it is a class III device as defined by section 513(f) of the Act for which there is in effect neither an approved premarket approval application under section 515(a) of the Act nor an approved investigational device exemption under section 520(g) of the act.

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 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 correct promptly 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 your receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should include steps 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.

Your response should be sent to Terri Garvin, 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 Jersey District. Please send a copy of your response to the District Director, 10 Waterview Boulevard, 3rd Floor, Parsippany, NJ 07054.

Sincerely yours,



 Larry Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health