



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m3021

APR 19 2000

WARNING LETTER

Food and Drug Administration  
Center for Devices and  
Radiological Health  
2098 Gaither Road  
Rockville, MD 20850

VIA FEDERAL EXPRESS

VIA FACSIMILE

David E.I. Pyott  
President and Chief Executive Officer  
Allergan, Inc.  
2525 Dupont Drive  
P.O. Box 19534  
Irvine, California 92623-9534

Re: AMO PhacoFlex II IOL (P880081)

Dear Mr. Pyott:

The Food and Drug Administration (FDA) has reviewed promotional materials for the AMO PhacoFlex II Intraocular Lens. This product is manufactured by Allergan, Inc., and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The AMO PhacoFlex IOL is indicated 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 extracapsular cataract extraction or phacoemulsification. These devices are intended to be placed in the ciliary sulcus or capsular bag.

The promotional material consists of: (1) an advertisement for the AMO PhacoFlex II appearing in the June 15, 1999, edition of *Ocular Surgery News*; (2) a June 3, 1999, "Dear Doctor" letter from Kevin Shearer, Allergan Senior Territory Manager to Eye Associates Northwest; (3) an undated "Dear Doctor" letter from Andy Stapars, Allergan Director of Marketing, US IOLs, reportedly mailed to ophthalmic surgeons in October 1999; (4) a two-page advertisement in the November 1, 1999, edition of *Ocular Surgery News*, entitled "The true story on PCO unfolds"; and (5) a hand-out obtained at the American Academy of Ophthalmology (AAO) in Orlando, Florida the week of October 24, 1999, entitled "It's official. The first and *only* FDA-approved PCO claim\*."

Several of the promotional pieces indicate that the PhacoFlex Lens may be inserted through unenlarged incisions of 2.6mm, 2.8mm, and 3.0mm. These sizes are a reduction from the PMA-approved incision size of 3.2mm. Allergan has not documented the claims of insertion through smaller incisions. There are also several references to benefits of "true micro-incision surgery," which is an unsubstantiated claim.

Promotional item #1 above contains several objectionable claims. It states "AMO PhacoFlex II... offers (b)enefits such as no induced astigmatism, long-term wound stability and reduced complications associated with wound enlargement." Although Allergan did submit a PMA supplement (S8) requesting approval to make similar claims, FDA sent a deficiency letter on September 25, 1991. Allergan never responded to that letter and the PMA supplement was considered withdrawn. Allergan never received approval to make these claims. A claim is also made that Proprietary SLM2 materials with a 6.0mm optic offers the highest refractive index. This is untrue, as there are other materials commercially available that have a higher refractive index.

Promotional item #2 above states "SI-40 foldable lenses are the gold standard in the foldable lens arena with the Unfolder Lens insertion system and equal or lower levels of inflammation, Yag and PCO rate as compared with other lenses." We wish to note that, while Allergan did obtain approval in Supplement 24

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to make labeling changes “to incorporate recent findings regarding the comparative incidence of posterior capsule opacification and Nd:YAG capsulotomy with silicone IOLs approved under this PMA versus polymethylmethacrylate (PMMA) IOLs,” that approval was not issued until July 2, 1999, after the “Dear Doctor” letter was sent. Thus, at the time, this was an unapproved claim.

Additionally, Allergan’s capsulotomy and posterior capsule opacification (PCO) value claims did not establish the SI-40 lens as the gold standard or that it was better than “other lenses.” The approval under Supplement 24 allowed Allergan to make comparative claims of PCO and Nd:YAG capsulotomy rates between Allergan’s SLM-2UV silicone IOLs and PMMA IOLs. However, Allergan did not get approval to make claims about “lower levels of inflammation,” and did not get approval to make comparative claims between its silicone IOLs and Alcon’s AcrySof IOLs (which are not PMMA).

Promotional items #3, #4, and #5 all contain claims comparing the AMO PhacoFlex to IOLs other than the PMMA IOL, i.e., square-edged IOLs, the AcrySof IOL and the ARRAY Multifocal IOL. Allergan’s comparisons of PCO and Nd:YAG rates are inappropriate. The safety and effectiveness data upon which the PMA was approved for the device was based on clinical data comparing the AMO PhacoFlex IOL to PMMA IOLs only. It is also inappropriate for Allergan to compare any SLM-2 lenses other than the Model SI30. The SI30 is the lens upon which the PCO value and YAG claims were based.

Allergan also claims to be “the only company with FDA-approved labeling documenting lower PCO values....” Alcon Laboratories also has approval, so this is an incorrect statement.

The approval order for your lenses stated that CDRH’s approval was subject to full compliance with conditions, including the condition that no advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to the device would recommend or imply that the device could be used for any use not included in the FDA-approved labeling for the device.

The AMO PhacoFlex II IOL is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket (PMA) in effect pursuant to section 515(a), or an approved application for investigational device exemption (IDE) under section 520(g).

The AMO PhacoFlex II IOL is also misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in 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 to be substantially equivalent to a predicate device. 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 and effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which FDA had advised that an alternate submission is permitted. In our opinion, the claims as noted above represent a change in the approved effectiveness of the device.

In addition, when false or misleading representations are made with respect to another device, it misbrands your device under 21 CFR 801.6.

The sale, distribution, and use of the AMO PhacoFlex II IOL is restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Act, under the authority of section 515(d)(1)(B)(ii) of the Act. FDA also determined that, to ensure the safe and effective use of the device, it was necessary to further restrict the device within the meaning of section 520(e) under authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and 502(r) of the Act. The “Conditions of Approval” that accompany your PMA approval order, under the heading entitled “ADVERTISEMENT,” states that “if the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being

imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.”

Therefore, in accordance with 21 CFR 801.109(d) and 502(r) of the Act, we believe that Allergan’s promotional materials should include a brief statement of the intended uses of the device, and the relevant warnings, precautions, side effects, and contraindications.

Please note that referring readers to the product labeling is not a substitute for the required information. Readers may be directed to the device’s labeling, physician’s manual, or patient information booklet for a **complete** listing of these items, but the advertising material must still include the brief statement of the intended uses and relevant warnings, precautions, side effects and contraindications.

Section 502(r) makes no reference or distinction as to whom this information is directed to, i.e., physician or lay consumer. Consumers, whether health care professionals or lay users, want to be able to compare devices or to compare the device with an alternative approach to treatment. Advertising is a particularly important source for comparative information, and provides both positive and negative information that sets one device apart from other similar devices or from alternatives.

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

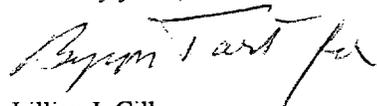
You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions 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 Ms. Patricia L. Jahnes, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-300), 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 Los Angeles District Office. Please send a copy of your response to the District Director, Food and Drug Administration, 19900 MacArthur Boulevard, Suite 300, Irvine, California 92612-2445.

Sincerely yours,



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