DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Timothy S. Adkins
Associate Director, Regulatory Affairs
Alcon Research Ltd.
6201 South Freeway
Fort Worth, TX 76134

MAY 03 2011

Re: P930014/S45
ACRYSOF® Toric Posterior Chamber Intraocular Lens Models SN60T6, SN60T7, SN60T8, and SN60T9; and AcrySof® IQ Toric Posterior Chamber Intraocular Lens Models SN6AT6, SN6AT7, SN6AT8, and SN6AT9
Filed: August 31, 2010
Amended: September 20, December 17, 2010, and March 11, 2011
Procode: HQL

Dear Mr. Adkins:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for the ACRYSOF® Toric Posterior Chamber Intraocular Lens Models SN60T6, SN60T7, SN60T8, and SN60T9; and AcrySof® IQ Toric Posterior Chamber Intraocular Lens Models SN6AT6, SN6AT7, SN6AT8, and SN6AT9. This device is indicated for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision. We are pleased to inform you that the PMA supplement is approved. You may begin commercial distribution of the device as modified in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that this restriction on sale and distribution is necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 5 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of this PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" (please use this title even if the specified interval is more frequent than one year) and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in separate post-approval study (PAS) reports. As a condition of approval, you must conduct the following post-approval study:

The New Enrollment Post-Approval Study: Per our agreement via email dated March 14, 2011, this study will address the following question: Is the rate of severe visual distortions reported in the IQ Toric High Cylinder Power study group (IOL Models SN6AT6-SN6AT9) different when compared to Alcon's previously approved similar devices? This study will be conducted in two phases:

a. Validation Phase: Before starting enrollment in the PAS, you will develop and validate the "Assessment of Photic Phenomena and Lens EffectS" (APPLES) questionnaire. You will conduct standard qualitative and quantitative validation of the questionnaire. The *qualitative* validation will consist of cognitive debriefing interviews with approximately 6 to 7 patients in each of the targeted populations (astigmatic/monofocal group, Alcon low cylinder toric and Alcon high cylinder toric groups), recruited from up to 5 investigative sites, to establish: (1) clarity of the items within the instrument; (2) how the respondents interpret the item(s); (3) ease of completion of the patient reported outcomes (PROs); (4) the comprehensiveness of the PROs; and (5) the appropriateness of the format, response scales, and recall period used in the PROs. Results of the cognitive debriefing will be evaluated after completion of approximately 50% of patients in each group to determine the need to modify the instrument. The *quantitative* validation will include the following activities: (1) conduct a validation study with up to 50 subjects composed of a balanced number of patients (approximately 15) in each of the targeted populations (astigmatic patients having received monofocal IOLs, low astigmatic patients having received the Alcon low cylinder Toric IOL and astigmatic patients receiving the Alcon high cylinder

Toric IOL) in up to 12 clinical investigative sites; and (2) a cross-sectional design with a second visit (~7 days subsequent to the baseline visit) for 50% of each of the specified target population to examine test-retest reliability.

The full validation of the APPLES questionnaire should be completed within seven months. The findings of the Validation Phase will be included as part of your post-approval study interim reports.

b. PAS Phase: This phase will consist of a multicenter, observational, prospective, 3-arm study. The first arm will receive the study device, and will consist of patients with bilateral cataracts and ≥ 2.57 D of pre-existing corneal astigmatism who are bilaterally implanted with the IQ Toric High Cylinder Power IOL Models SN6AT6-SN6AT9. The other two arms will be the comparison groups. The second arm will consist of patients with bilateral cataracts and ≥ 2.57 D of pre-existing corneal astigmatism, who are bilaterally implanted with the non-toric monofocal IOL Model SN60WF. The third arm will consist of patients with bilateral cataracts and 0.90 D to 2.56 D of pre-existing corneal astigmatism, who are bilaterally implanted with the IQ Toric IOL models SN6AT3, or SN6AT4 or SN6AT5.

A total of 925 subjects treated by newly trained surgeons, at a minimum of 50 and up to 100 investigational sites, will be enrolled. A minimum of 250 subjects in each arm are required for the primary analysis. The study participants will be followed at Day 7-14 and Day 120-180. For those patients who reported severe visual distortion(s) and / or have a Secondary Surgical Intervention (SSI) a final visit will take place at Day 330-420. Effectiveness will be evaluated by PROs on visual distortions. The effectiveness hypotheses will be evaluated 6-months post-implant.

In addition to the severe visual distortions, the safety of the device will also be evaluated by providing descriptive data on adverse events such as lens dislocation, papillary block, ocular SSI, SSI due to visual distortions, and any other vision-threatening adverse event related to the IOL.

Please be advised that the results from these studies should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

FDA would like to remind you that you are required to submit PAS Progress Reports every six months during the first two years and annually thereafter. The reports should clearly be identified as Post-Approval Study Report. Two copies, identified as "PMA Post-Approval

Study Report" and bearing the applicable PMA reference number, should be submitted to the address below. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm

Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval study. Your PMA supplement should be clearly labeled as a "Post-Approval Study Protocol" and submitted in triplicate to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

Before making any change affecting the safety or effectiveness of the device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

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CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. Final printed labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing. One of those three copies may be an electronic copy (eCopy), in an electronic format that FDA can process, review and archive (general information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm; clinical and statistical data: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm)

U.S. Food and Drug Administration
Center for Devices and Radiological Health
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10903 New Hampshire Avenue
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If you have any questions concerning this approval order, please contact Marc Robboy, O.D. at 301-796-6860.

Sincerely yours,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Division Director
Division of Ophthalmic, Neurological, and
Ear, Nose and Throat Devices
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