Date: 11/18/99
From: Medical Officer, Vitreoretinal and Extraocular Branch, HFZ-460,
Linda Lee Cohen, M.D., MS., MPH LLC
Subject: Review of Citizen Petition to Reclassify Artificial Eye Lubricants
Sponsor: Elliott Farber, Ph.D. of E. F. Associates, Consultant for Alwyn Company Inc.
To: The Record

Section under which the petition is submitted: The petitioner, Elliott Farber, Ph.D., has requested reclassification under Section 513(e) of the Food and Drug Administration Act which for reclassification based on new information (See Code of Federal Regulations Section 860.130), submitted in response to the petition of an interested person, Subsection (b)3 which is for reclassification based upon new information. The new information is that the product, a lubricant, is an accessory to a reclassified device, artificial eyes, and that adequate standards are available. Additionally, Section 520(1) of the act (CFR 860.136) provides for reclassification of transitional products when petitioned by FDA, an importer or manufacturer. Dr. Farber is a consultant to the manufacturer, Alwyn Company, Inc. The Section applies to transitional devices regarded as "new drugs" before May 28, 1976. The artificial eye lubricant can be categorized under both Sections. Each section requires that the information submitted be filed in accordance with Section 860.123.

Reviewed under Section 860.123, Reclassification petition: Content and Form, for what has been submitted for the reclassification. In accordance, the following are found:

_+_ 1. Specification of type of device: Ocular prosthetic (artificial eye) lubricant

_+_ 2. Action requested: Requested is that artificial eye lubricants (transitional devices) be reclassified from Class III to Class II

_+_ 3. Completed supplemental data sheet applicable to the device for which reclassification is requested: Form FDA 3427 (2/97) has been submitted.

_+_ 4. Completed classification questionnaire applicable to the device: Form FDA 3429 (2/97) has been submitted.

_+_ 5. Statement of the basis for disagreement with the present classification: The ocular prosthetic, or artificial eye, is a cosmetic device to improve physical appearance and is not life threatening or potentially hazardous to life. It has been reclassified from Class III to Class I. The less stringent requirements of Class II are sufficient to reasonably assure safety and effectiveness of the lubricant for the Class I device.

+- 6. Full statement of the reasons, together with supporting data to satisfy the requirements of 860.7, Contents of Standards, showing why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device: Set performance standards under Class II for sterility, toxicity and irritation can reasonably assure safety and effectiveness. Sterility of the artificial eye lubricant can minimize the possibility of infection. Supporting information other than the attachment with directions for use was not submitted. The Supplementary Data Sheet identifies as a risk the possibility of: 1) infection which can be minimized by sterilizing the device, 2) toxicity potential that can be reduced by using only a non-toxic device, and 3) potential for irritation that is minimized by using a non-irritating device. NO SUPPORTING DATA IS SUBMITTED. However, the annual reports for a marketed NDA artificial eye lubricant that have been reviewed for the last three years have not included any adverse reactions.

+- 7. Representative data and information known to the petitioner that are unfavorable to the petitioner's position: No data and no information are submitted about known infections, toxicity or irritation.

NA 8. A summary of new information, if the petition is based on new information under 513(e) 514(b) or 515(b): The petition is not based on new information other than the fact that the device is an accessory to a device that has been reclassified from Class III to Class I.

NA 9. Copies of source documents from which new information used to support the petition has been obtained (attached as appendices to the petition)

NA 10. A financial statement or disclosure statement or both as required by part 54 of this chapter. There are no clinical investigators for whom financial disclosure is required.

Comment: The artificial eye lubricant provides a useful purpose that facilitates use of the eye without irritation and resultant infection of the conjunctiva of the orbit. Although allergic or toxic reactions and infections especially with unsterile lubricants or improper use are possible, the FDA does not have reported problems associated with one lubricant marketed under an approved NDA and does not anticipate any safety or effectiveness problems when the lubricant meets standards and is properly used. A literature review is being done.

Recommendation: Approval of reclassification from Class III to Class II with the meeting of appropriate standards.

Linda Lee Cohen, M.D.