DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-213/S-010

Novartis Pharmaceuticals Corporation
Attention: Jeannie Shen
Associate Director, Global Regulatory CMC
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Shen:

Please refer to your supplemental new drug application dated October 14, 2005, received October 17, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Miochol-E (acetylcholine chloride for intraocular solution).

Your submission of March 20, 2006, constituted a complete response to our February 17, 2006, action letter.

This supplemental new drug application provides for:

A. Changes to the drug product:

1. Additional site for:
   - Manufacturing and testing for the drug product at Novartis Pharma Stein AG
   - (b)(4) for the blistered vial and ampoules at (b)(4)
   - Stability testing at Novartis Pharmanalytica S.A. (b)(4)
   - Secondary packaging at (b)(4)
2. Change in drug product container packaging to a vial containing the acetylcholine chloride 20 mg and an accompanying ampoule for the 2 mL diluent for reconstitution.
3. Increase in batch size for the Miochol-E 20 mg vials and the diluent ampoules.
4. Minor changes in the manufacture of the drug product, including changes in the in-process controls.

B. Updates to the package insert and carton label to reflect the manufacturing changes.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as described in the enclosed labeling text. The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert submitted October 14, 2005.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory*

Submissions in Electronic Format - NDAs (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format with proposed revisions clearly indicated, preferably in track changes. If formatted copies of all labeling pieces are submitted electronically, labeling does not need to be submitted in paper.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lori M. Gorski, Project Manager, at (301) 796-0722.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Wiley Chambers
5/30/2006 05:01:46 PM
for Janice Soreth