U.S. FOOD & DRUG ADMINISTRATION

Deborah Livornese
Hyman Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Re: Docket No. FDA-2019-P-0372

JUL 16 2019

Dear Ms. Livornese:

This letter responds to your citizen petition received on January 23, 2019 (Petition). In your Petition, you request that the Food and Drug Administration (FDA) determine whether Miochol (acetylcholine chloride intraocular solution), 20 milligrams (mg)/vial, approved under new drug application 016211, held by Novartis Pharmaceuticals Corp., has been voluntarily withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Miochol (acetycholine chloride intraocular solution), 20 mg/vial, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Miochol (acetycholine chloride intraocular solution), 20 mg/vial, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-1830.

Sincerely,

for

Meadow Platt
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov