DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

January 24, 2019

Deborah Livornese
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Sent via email: DLivornese@hpm.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine whether MIOCHOL (acetylcholine chloride for intraocular solution, approve under New Drug Application ("NDA") number 016211, held by Novartis Pharmaceuticals Corp., has been voluntarily withdrawn for reasons of safety or effectiveness was received by this office on 1/23/2019.

It was assigned docket number FDA-2019-P-0372. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karend Kennard
Acting Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)