DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

May 2, 2013

Amanda Dixon
Director of Regulatory Affairs and Quality
Nomax, Inc
9734 Green Park Industrial Drive
St. Louis, MO 63123

Dear Ms. Dixon:

Your petition to the Food and Drug Administration requesting for a change in dosage form (from an intravenous solution of fluorescein sodium) to a sterile strip impregnated with fluorescein sodium, a change in strength from a 10% solution (100 mg fluorescein sodium per milliliter) to 0.6 or 1 mg of fluorescein sodium absorbed into a sterile strip, and for a different route of administration (intravenous and intradermal, for the reference listed drug to intraocular instillation for the proposed generic drug, was received by this office on 05/02/2013. It was assigned docket number FDA-2013-P-0505/CP1, and it was filed on 05/02/2013. 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,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)