Public Health Service

Food and Drug Administration Rockville, MD 20857

August 6, 2003

FILE COPY

Wendy S. Vicente Fish and Richardson, P.C. 1425 K Street, N.W. 11th Floor Washington, DC 20005

Dear Ms. Vicente:

Your petition on behalf of Allergan, Inc. requesting the Food and Drug Administration to stay its approval of all Section 505(j) Abbreviated New Drug Applications and Section 505(b)(2) New Drug Applications for generic versions of Restasis®, Ophthalmic Emulsion 0.05% was received by this office on August 6, 2003. It was assigned docket number 2003P-0275/PSA 1 and it was filed on August 6, 2003.

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.

Lyle D. ¥affe Division of Dockets Management

2003P.0215

