ALLERGAN

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July 30, 2003

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

RE: NDA 50-790 (formerly 21-023)
RESTASIS™ (cyclosporine ophthalmic emulsion) 0.05%

Dear Orange Book Staff:

Allergan is notifying your office that the current Orange book shows no patent protection for Allergan's RESTASIS™ (cyclosporine ophthalmic emulsion) 0.05%. The following information is being supplied so that the omission can be corrected.

Trade Name: RESTASIS™
Active Ingredient: cyclosporine
Strength: 0.05%
Dosage Form: Ophthalmic emulsion
Approval Date: December 23, 2002

The following patents are place for RESTASIS™ (cyclosporine ophthalmic emulsion) 0.05%:

Patent Number	Patent Title	Expiration Date
US 4,649,047	Ophthalmic Treatment by Topical Administration of Cyclosporin	March 19, 2005
US 4,839,342	Method of Increasing Tear Production by Topical Administration of Cyclosporin	August 2, 2009
US 5,474,979	Nonirritating Emulsion for Sensitive Tissue	May 17, 2014

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Our original NDA stated an expiration date of June 13, 2006 for patent number 4,839,342. Please note the term of this patent has been extended to the date listed in the table above. Allergan is requesting that this patent information be included in the Orange Book at your earliest opportunity.

The undersigned declares that the above stated United States Patent Numbers 4,649,047; 4,839,342 and 5,474,979 cover the formulation, composition, and/or method for use of cyclosporine A. This product is currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

Should you require additional information, you may contact me by telephone at 714-246-4391, by fax at 714-246-4272, or E-mail at bancroft_elizabeth@allergan.com.

Sincerely,

Peter O. Kreuk

for Elizabeth Bancroft
Senior Director
Regulatory Affairs

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