DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 15 2003

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Terry G. Mahn
John E. Mauk
Wendy S. Vicente
Fish & Richardson P.C.
1425 K Street
11th Floor
Washington D.C. 20005

Donald O. Beers
Grant P. Bagley
Arnold & Porter
555 Twelfth Street, NW
Washington, D.C. 20004

Re: 2003P-0275/CP1 & PSA1

Dear Mr. Mahn, Mr. Mauk, Ms. Vicente, Mr. Beers, and Mr. Bagley:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on June 13, 2003 on behalf of Allergan, Inc. You request that FDA reclassify cyclosporine as a "non-antibiotic drug" and remove it from the proposed list of drugs that are ineligible for marketing exclusivity and patent listing pursuant to section 125(d) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105-115). In the alternative, you request that FDA find that Restasis (cyclosporine ophthalmic emulsion) 0.05% is not an antibiotic drug product that falls under the transition provisions of section 125(d) of the Modernization Act and grant Restasis three-year marketing exclusivity and patent listing rights under section 505 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355).

FDA previously notified Mr. Beers that the agency intended to respond to the petition by December 15, 2003. We have been carefully considering all of the issues raised in the petition and working diligently to complete our response. We are in the process of finalizing our response, and we will send it to you no later than December 18, 2003, and sooner if we are able to do so. In addition, pursuant to the December 2, 2003 Order issued by the United States District Court for the District of Columbia in Allergan, Inc. v. McClellan, et al., 1:03-cv-2236, we will produce and file the administrative record of FDA's March 3, 2003 decision no later than December 19, 2003.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2003P-0275

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