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AUGUST 1, 2003

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852



RE: Docket No. 2003P-275/CP-1

BOSTON

DALLAS

DELAWARE

NEW YORK

SAN DIEGO

SILICON VALLEY

TWIN CITIES

WASHINGTON, DC

Dear Sir or Madam:

Allergan, Inc. hereby submits an amendment to its Citizen Petition, Docket No. 2003P-275/CP-1, filed June 13, 2003. The enclosed declaration of Stephen Johnson clarifies that Allergan has spent over \$47 million to date for research and development for Restasis®.

In addition, Allergan submits a petition to stay FDA approvals of generic drugs for Restasis®. The enclosed petition also requests that FDA list Allergan's patents for Restasis® in the Orange Book. These papers are being concurrently sent to FDA's General Counsel, Mr. Daniel Troy. Thank you for your timely consideration of these matters.

Respectfully submitted,

Terry G. Mahn
Wendy S. Vicente
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Enclosures

2003P-0275

SUP 1

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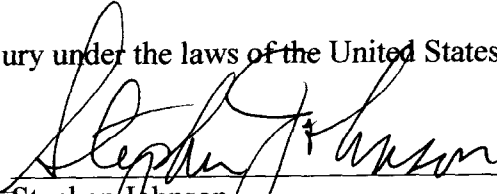
DOCKET NO. 2003P-275/CP-1

DECLARATION OF STEPHEN JOHNSON
IN SUPPORT OF ALLERGAN'S CITIZEN PETITION

I, Stephen Johnson, declare as follows:

1. I am the Vice President of Project Management for Allergan Research and Development. I have held that position since March 1997.
2. As part of my responsibilities, I retain cost records for the drug products that Allergan is developing, including Restasis®, which is the subject of Allergan's Citizen Petition ("CP"), Docket No. 2003P-275/CP-1.
3. I am aware that Allergan's CP states that Allergan has expended "more than \$5 million" on research, development, and clinical trials for Restasis®. CP at 11.
4. I make this declaration in support of that CP and to clarify the actual expenditures made by Allergan in support of Restasis®. As of March 31, 2003, Allergan has expended \$47,241,600 in its U.S.-based operations for Restasis®.
5. Specifically, Allergan's expenditures for Restasis® are as follows:
 - a.) \$ 4,635,900 for preclinical between January 1992 and March 1995;
 - b.) \$10,530,450 for Phases 1 and 2 clinical trials between March 1995 and July 1997;
 - c.) \$29,469,250 for Phase 3 clinical trials between July 1997 and January 2002;
 - d.) \$ 2,000,000 during final FDA review from January 2002 to December 2002; and
 - e.) \$ 606,000 in the first quarter of 2003.

I make this declaration under penalty of perjury under the laws of the United States, on this 30th day of July, 2003.



Stephen Johnson
V. P. R&D Project Management