DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-392/S-010

Mylan Pharmaceuticals, Inc
Attention: S. Wayne Talton
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Mr. Talton:

Please refer to your supplemental new drug application dated October 7, 2005, received October 11, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cystagon®(cysteamine bitartrate) Capsules, 50 mg and 150 mg.

We acknowledge receipt of your submissions dated December 6, 2006 and June 6, 2007.

Your submission of June 6, 2007 constituted a complete response to our April 11, 2006 action letter.

This supplemental new drug application provides for revisions in the **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the labeling regarding benign intracranial hypertension (or pseudotumor cerebri; PTC) and serious skin lesions.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with editorial revisions listed below and indicated in the enclosed labeling.

In the "Patient and Parent Information" section, "General Information about CYSTAGON®" subsection, in the second paragraph that begins with "For more information call 1-877-466-3678)" should read "For more information call 1-877-466-3678".

The final printed labeling (FPL) must be identical, and include the editorial revision indicated, to the enclosed labeling (text for the package insert) and/or submitted labeling (package insert submitted June 6, 2007).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-392/S-010**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Hyon-Zu Lee, Pharm.D., Regulatory Project Manager, at 301-796-2050.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Rafel Rieves

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