NDA 20-392/S-005

Mylan Pharmaceuticals, Inc. 06 APR 2001
Attention: Frank R. Sisto
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Mr. Sisto:

Please refer to your supplemental new drug application dated August 31, 2000, received September 1, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cystagon® (cysteamine bitartrate) Capsules.

We acknowledge receipt of your submissions dated March 29 and April 3, 2001.

This "Changes Being Effected" supplemental new drug application provides for revisions to the PRECAUTIONS section, Pregnancy subsection of the package insert.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted August 31, 2000) and include the text for the PRECAUTIONS section, Pregnancy subsection identical to that submitted April 3, 2001 in place of the text in the August 31, 2000 insert. These revisions are terms of the approval of this application. Please incorporate these revisions into the next printing of FPL.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-392/S-005." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Brian Strongin, Project Manager, at (301) 827-7310.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research