DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-539/S-004

Cumberland Pharmaceuticals, Inc.
Attention: Amy Rock, Ph.D.
Senior Scientist, Regulatory Affairs
2525 West End Avenue, Suite 950
Nashville, Tennessee 37203

Dear Dr. Rock:

Please refer to your supplemental new drug application dated August 16, 2005, received August 17, 2005, submitted pursuant to section 505 (b) of the Federal Food, Drug, and Cosmetic Act for ACETADOTE® (acetylcysteine) Injection.

We acknowledge receipt of your submission dated December 28, 2005; February 7, and February 10, 2006.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (package insert submitted of February 10, 2006).

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 21-539/S-004".** Approval of this submission by FDA is not required before the labeling is used.

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 Mary Lewis, Regulatory Project Manager, at (301) 796-0941.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
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/

Brian Harvey

2/15/2006 02:10:42 PM