DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-539 SLR 005 **NDA APPROVAL**

Cumberland Pharmaceuticals, Inc.
Attention: Amy Rock, PhD.
Senior Manager, Regulatory Affairs
2525 West End Avenue, Suite 950
Nashville TN 37203

Dear Dr. Rock:

Please refer to your labeling supplement submission for new drug application (NDA) 21-539 dated May 3, 2007, received May 4, 2007, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Acetadote (acetylcysteine) Injection 200mg/mL.

We acknowledge receipt of your subsequent amendments dated February 5, 2008, February 19, 2008, May 19, 2008, September 12, 2008, September 16, 2008, and November 11, 2008.

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

Section 6.1
The second paragraph under, "Loading Dose/Infusion Rate Study" will move to become the first paragraph (of the two proposed paragraphs in your November 11, 2008, submission) within the same section and study referenced.

Highlights of Prescribing Information
The revision date will be changed from 11/2008 to 12/2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert and submitted labeling package insert submitted September 18**,** 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-539."

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b) (3) (I), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), sees www.fda.gov/cder/ddmac.

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

Med Watch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Hee (Sheila) Lianos, Regulatory Project Manager, at (301) 796-4147.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.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/

Donna Griebel

12/12/2008 05:51:53 PM