DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-120/S-002

Collegium Pharmaceutical
400 Highland Corporate Drive
Cumberland, RI 02864-1788

Attention: Mr. Heow Tan
Vice President, Technical Operations

Dear Mr. Tan:

Please refer to your supplemental new drug application dated April 1, 2008, received April 4, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AllerNaze (triamcinolone acetonide) Nasal Spray 50 mcg.

We acknowledge receipt of your submissions dated July 30, August 18, and December 29, 2008.

This supplemental new drug application proposes revisions to the CMC information, including change in the composition, container-closure, manufacturing and quality control testing site, and revisions to the product labeling to change the name of the product from Tri-Nasal to AllerNaze.

We have 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.

CONTENT OF LABELING

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 submitted on December 29, 2008, and text for PATIENT INSTRUCTIONS FOR USE submitted on August 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 20-120/S-002".

CARTON AND IMMEDIATE CONTAINER LABELS:

We acknowledge your December 29, 2008, submission containing final printed carton and container labels.

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
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 Ladan Jafari, Regulatory Project Manager, at (301) 796-1231.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Pkg insert, Patient Instructions for Use

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

/s/

Badrul Chowdhury

1/7/2009 11:54:59 AM