DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12041/S-39
NDA 14901/S-39

SUPPLEMENT APPROVAL

Bristol-Myers Squibb
P.O. Box 4000
Princeton, NJ 08543-4000

Attention: Angela Glauberzon
Associate Director, Mature Products
Global Regulatory Sciences

Dear Ms. Glauberzon:

Please refer to your Supplemental New Drug Applications (sNDA) dated November 30, 2010, received December 1, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kenalog-10 (triamcinolone acetonide) Injection and Kenalog-40 (triamcinolone acetonide) Injection.

We acknowledge receipt of your amendments dated June 23, 2011.

These Changes Being Effected supplemental new drug applications provide revisions to the package insert to expand on information regarding anaphylaxis, in the Warnings and Adverse Reactions sections of the label.

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 agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Michelle Jordan Garner, Regulatory Project Manager, at (301) 796-4786.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, MD, PhD
Director
*Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

BADRUL A CHOWDHURY
07/15/2011