DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993

Our STN: BL 125118/86

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

Attention: Anand S. Achanta, Ph.D.
Director, Global Regulatory Sciences

Dear Dr. Achanta:

Please refer to your supplemental biologics license application dated October 27, 2008, received October 27, 2008, submitted under section 351 of the Public Health Service Act for ORENCIA® (abatacept).

We acknowledge receipt of your submissions dated December 28, 2008, and July 9 and August 19, 2009 and you email correspondence dated August 25, 2009.

This supplemental biologics license application provides for revisions to the **ADVERSE REACTIONS: Clinical Experience in MTX-Naïve Patients** and **CLINICAL STUDIES: Adult Rheumatoid Arthritis** sections of the Package Insert.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Pursuant to 21 CFR 201.57(c)(18) and 201.80(f)(2), patient labeling must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 125118/0086." In addition, within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

Please refer to http://www.fda.gov/cder/biologics/default.htm for information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

If you have any questions, call Christopher Hilfiger, Regulatory Project Manager, at (301) 796-4131.

Sincerely,

/Rigoberto Roca, MD/

Rigoberto Roca, MD
Deputy Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert
Patient Package Insert