DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103770/5113

MedImmune, Inc.
Attention: Steve Danielson
Director, Regulatory Affairs
One MedImmune Way
Gaithersburg, MD 20878

**August 1, 2008**

Dear Mr. Danielson:

Your request to supplement your biologics license application (BLA) for Synagis® (palivizumab) to revise the ADVERSE REACTIONS, Postmarketing Reaction subsection with information related to thrombocytopenia and injection site reactions has been approved.

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

We note your June 30, 2008 submission included final content of labeling [CFR 601.14(b)] in structured product labeling (SPL) format; we will transmit it to the National Library of Medicine for public dissemination. 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.

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

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

Sincerely,

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research