DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103770/5096

February 28, 2007

MedImmune, Inc.
Attention: Ross Lobell
Senior Director Regulatory Affairs
One MedImmune Way
Gaithersburg, MD 20878

Dear Mr. Lobell:

Your request to supplement your biologics license application (BLA) for Synagis®, palivizumab, to delete the lyophilized formulation information from the DESCRIPTION, DOSAGE AND ADMINISTRATION, and HOW SUPPLIED sections of the package insert and to revise the CLINICIAL PHARMACOLOGY, WARNINGS, and ADVERSE REACTIONS, Immunogenicity sections of the package insert has been approved.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and the submitted labeling (immediate container and carton labels submitted January 31, 2007). Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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