DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Our STN: 103770/5116

March 23, 2009

MedImmune, LLC
Attention: Steve Danielson
Associate Director, Regulatory Affairs
One MedImmune Way
Gaithersburg, MD 20878

Dear Mr. Danielson:

Please refer to your supplemental biologics license application dated and received on January 7, 2008, for Synagis® (palivizumab) submitted under section 351 of the Public Health Service Act.

We acknowledge receipt of your submission dated October 31, 2008.

This supplemental new biologics application was submitted to provide a new patient package insert.

We 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 (package insert and patient package insert). 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 BLA 103770/5116."**

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 and in the required format may render the product misbranded and an unapproved product.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this BLA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Sherly Abraham, R.Ph., Regulatory Project Manager, at (301) 796-3198.

Sincerely,

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

Enclosure: Package Insert
Patient Package Insert