DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 103770/5059

MedImmune, Incorporated
Attention: Peter Patriarca, M.D.
Vice President, Regulatory Affairs
One MedImmune Way
Gaithersburg, MD 20898

Dear Dr. Patriarca:

Your request to supplement your biologics license application for Palivizumab, to provide 50 mg and 100 mg liquid formulations in single-dose vials has been approved.

The dating period for Palivizumab liquid formulation drug product shall be 24 months from the date of manufacture when stored at 2-8 degrees C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. The dating period for your drug substance shall be 9 months when stored at 2-8 degrees C. We have approved the stability protocol SP-76107 in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

Results of ongoing stability studies should be submitted throughout the dating period, as they become available, including the results of stability studies from the first three production lots.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We acknowledge your written commitment to conduct a postmarketing study as described in your letter of July 9, 2004, outlined below:

Postmarketing Studies subject to reporting requirements of 21 CFR 601.70.

To conduct an immunogenicity study, MEDI-493, entitled "A Phase IV, Double-Blind Study to Assess the Immune Reactivity of the Liquid and Lyophilized Formulations of Palivizumab in Children at High Risk for the Development of Serious RSV Disease." You will submit validation of the bioassay prior to conducting the immunogenicity study. The final protocol for this study will be submitted by April 30, 2005, and patient accrual will be completed by December 31, 2005. The study will be completed by October 31, 2006, and the final study report will be submitted by April 30, 2007.

We request that you submit clinical protocols to your IND, with a cross-reference letter to this biologics license application (BLA), STN BL 103770. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to your BLA, STN BL 103770. Please use the following designators to label prominently all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Study Protocol**
- **Postmarketing Study Final Report**
- **Postmarketing Study Correspondence**
- **Annual Report on Postmarketing Studies**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. The status report for each study should include:

- information to identify and describe the postmarketing commitment,
- the original schedule for the commitment,
- the status of the commitment (i.e. pending, ongoing, delayed, terminated, or submitted), and
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e. number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our Web site (http://www.fda.gov/cder/pmc/default.htm). Please refer to the April 2001 Draft Guidance for Industry: Reports on the Status of Postmarketing Studies – Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (see http://www.fda.gov/cber/gdlns/post040401.htm) for further information.

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).

The regulatory responsibility for review and continuing oversight for this product transferred from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research effective June 30, 2003. For further information about the transfer, please see http://www.fda.gov/cder/biologics/default.htm. Until further notice, however, all correspondence, except as provided elsewhere in this letter, should continue to be addressed to:

CBER Document Control Center
Attn: Office of Therapeutics Research and Review
Suite 200N (HFM-99)
1401 Rockville Pike
Rockville, Maryland 20852-1448

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

Sincerely,

Marc Walton, M.D., Ph.D.
Director
Division of Therapeutic Biological Internal Medicine Products
Office of Drug Evaluation VI
Center for Drug Evaluation and Research

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cc: HFM-585/ DARP BLA file
HFM-561/ S. Kozlowski
HFM-555/ P. Swann
HFM-500/ OTRR Office Director
HFM-672/ Product Release Staff Director, HFM-672 (if non-specified product)
HFD-322/ E. Rivera-Martinez, IPCB
HFM-4/ QAS
HFM-110/ RIMS
HFM-670/ DMPQ Blue file
HFD-320/DMPQ Division Director
HFM-599/ M. Smedley
HFM-599/ C. Renshaw
HFM-599/ J. Kutza

History: (b)(4) -- --------: 7.23.04

File Name: (b)(4) ----- 103770.5059/061704.approval letter

Office	Name/Signature	Date