DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103770/ 5153

SUPPLEMENT BLA APPROVAL
April 4, 2011

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

Dear Mr. Danielson:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received July 14, 2010, submitted under section 351 of the Public Health Service Act for Synagis® (palivizumab).

We acknowledge receipt of your amendments dated August 19, 2010, November 19, 2010, and December 13, 2010 and March 18, 2011.

This "Changes Being Effected" labeling supplement to your biologics license application proposes the following changes:

Package insert:

- to add in the Warnings section "Cases of anaphylaxis and anaphylactic shock, including fatal cases" have been reported following initial exposure or re-exposure to Synagis".

- to move the information on symptoms of acute hypersensitivity from the Post-Marketing Experience section, and to add the symptom of hypotension to the Warnings section.

Patient Package Insert:

- to add "a drop in blood pressure" to the "Who should not receive Synagis?" and

- to add "Such reactions may be life-threatening or cause death" to the "Possible, serious side effects include" section.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. For administrative purposes, please designate this submission "**Product Correspondence – Final SPL for approved BLA STN 103770/5153**."

Also within 14 days, amend all pending supplemental applications for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

The SPL will be accessible via publicly available labeling repositories.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this BLA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

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

Sincerely,

/ Kendall Marcus, M.D. /
Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling