DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19430/S-058

SUPPLEMENT APPROVAL

Mylan Specialty, L.P.
781 Chestnut Ridge Road
Morgantown, WV 26504-4310

Attention: Dawn Watson, Ph.D.
Vice President Regulatory Affairs

Dear Dr. Watson:

Please refer to your Supplemental New Drug Application (sNDA) dated October 23, 2013, received October 24, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EpiPen and EpiPen Jr Auto-Injector (epinephrine) Injector 0.3 mg/0.3mL and 0.15 mg/0.3mL.

We acknowledge receipt of your amendments dated February 28, March 19, April 29, and July 7, 2014.

This Prior Approval supplemental new drug application proposes to update the carton labels to provide a visual summary of the three steps (Prepare, Administer, and Finalize) used to administer EpiPen, and to ensure that the administration summaries on the carton, container, and trainer labels match the three steps for administration of EpiPen in the approved instructions for use.

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.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 19430/S-058**." Approval of this submission by FDA is not required before the labeling is used.

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

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Carol F. Hill, Safety Regulatory Project Manager, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Lydia Gilbert-McClain, M.D.
Deputy Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LYDIA I GILBERT MCCLAIN
07/17/2014