



NDA 19-430/SLR-047

Meridian Medical Technologies, Inc.  
1945 Craig Road  
St. Louis, MO 63146

Attention: Ellen Kay Losciuto  
Senior Regulatory Affairs

Dear Ms. Losciuto:

Please refer to your supplemental new drug application dated November 18, 2008, received November 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EpiPen and EpiPen Jr Auto-Injectors (epinephrine injection) solution, 0.3mg/ml and 0.415/0.3 ml.

We acknowledge receipt of your submission, dated May 5, 2009.

This supplemental new drug application provides for change in color of the nose cone and needle cover; change in the color of the safety release; addition of an orange band with black arrows and the words "needle end" indicating the needle end of the auto-injector; revisions to the trainer insert and patient instructions sheet to reflect the color changes; and minor editorial revisions and relocation of some of the text in the patient instructions sheet and carton and container labels.

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 and with the minor editorial revisions listed below/indicated in the enclosed labeling.

1. Revise the first sentence of the first paragraph in the INDICATIONS AND USAGE section of the label to read, "who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions."

Within 14 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the submitted attached labeling (package insert submitted, December 2, 2008). 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 NDA 19-430/S-047.**"

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels (submitted on November 18, 2008) 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 titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. 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 19-430/S047.**” Approval of this submission by FDA is not required before the labeling is used.

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 Hill, Regulatory Health Project Manager, at (301) 796-1226.

Sincerely,

*{See appended electronic signature page}*

Badrul A. Chowdhury, M.D., Ph.D.  
Division Director  
Division of Pulmonary and Allergy Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure Package Insert

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Sally Seymour  
5/19/2009 04:46:45 PM  
for Badrul Chowdhury