



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-430/S-044

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 July 31, 2007, received August 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EpiPen and EpiPen Jr Auto-Injectors.

We acknowledge receipt of your submissions dated January 11 and 28, February 7, March 25, July 10, and September 22 and 25, 2008.

Your submission of March 25, 2008 constituted a complete response to our February 1, 2008 action letter.

This supplemental new drug application provides for changes to the patient insert, trainer insert, carton and container labeling to reflect the change in design of the auto-injector.

We have 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.

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, September 25, 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-044.”**

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels (carton submitted on March 25, 2008 and immediate container submitted on July 31, 2007) 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/S044.**” 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

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

Badrul Chowdhury
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