



NDA 19-430/S-025

Meridian Medical Technologies
2550 Hermelin Drive
St. Louis MO 63144- 2591

Attention: Ellen Kay Losciuto
Regulatory Affairs Specialist

Dear Ms. Losciuto:

Please refer to your supplemental new drug application dated June 16, 2003, received June 17, 2003, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for EpiPen and EpiPen Jr. (epinephrine injection) 0.3 mg and 0.15 mg.

This supplemental new drug application provides for a change in the color of the EpiPen Jr. carton and container label and a change in font for the term "Jr."

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 16, 2003.

We remind you of the telephone conversation on December 17, 2003 between you and Sandy Barnes of this Division in which you agreed to revise the white on green coloring on the carton and container to black on green within 8 months.

In addition, if space permits we recommend adding the statements "Never put thumb, fingers or hand over black tip." and "Do NOT remove gray activation cap until ready to use." to the carton and container labeling for EpiPen and EpiPen Jr.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ladan Jafari, Regulatory Project Manager, at (301) 827-1084.

Sincerely,

{See appended electronic signature page}

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

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

Eugene Sullivan
12/17/03 03:32:50 PM
For Badrul A. Chowdhury, MD