CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-430/S056

Trade Name: EpiPen®

Generic Name: epinephrine

Sponsor: Mylan Specialty L.P.

Approval Date: 11/8/2013

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APPLICATION NUMBER:

19-430/s056

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

19-430/s056

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19430/S-056

APPROVAL LETTER

Meridian Medical Technologies, Inc.
Attention: Ellen Kay Losciuto
Manager, Regulatory Affairs
1945 Craig Road
St. Louis, MO 63146

Dear Ms. Losciuto:

Please refer to your Supplemental New Drug Application (sNDA) dated May 10, 2013 and received May 13, 2013, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EpiPen® and EpiPen® Jr (Epinephrine) Auto-Injector.

This "Changes Being Effected" supplemental application provides for an explanation of a previously approved change in the (b) (4).

We have completed our review of this supplemental new drug application. This supplement is approved.

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 Youbang Liu, Regulatory Project Manager, at (301) 796-1926.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

RAMESH RAGHAVACHARI
11/08/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-430/s056

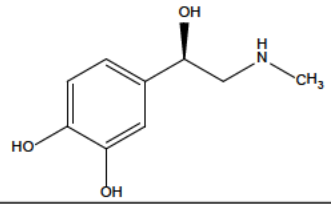
CHEMISTRY REVIEW(S)

Chemist Review: # 1	**1. Division:** DPARP	2. **NDA Number**: 019-430

3. Name and Address of Applicant: Meridian Medical Technologies Inc. 1945 Craig Road St Louis MO 63146	**4. Supplement Number**: **SCS-056** Date(s): May 10, 2013 received on May 13, 2013 **Paper Submission**
5. Name of Drug: Epi-Pen Auto Injector™	**6. Nonproprietary name:** Epinepherine Injection
7. Supplement (CBE-0) Provides for a revised [redacted] (b) (4) . Note: The proposed change was approved under the NDAs listed in Section 11.	**8. Amendment(s): N/A**

9. Pharmacological Category: Treatment of Anaphylaxis	**10. How Dispensed:** R_x	**11. Related Documents: Y** See NDA18-986/S040 (approved on 4/30/2008), [redacted] (b) (4) NDA 17-106/S044 (approved on 6/10/2010)
12. Dosage Form: Sterile Injectable Solution	**13. Potency:** 0.3 mg/0.3 mL, 0.15 mg/0.3 mL	

14. Chemical Name and Structure: *(R)*-4-(1-hydroxy-2-(methylamino)ethyl)benzene-1,2-diol



15. Comments: This CBE-0 supplement provides for a previously approved change in the [redacted] (b) (4) (see related NDA documents, in Section 11). As per the applicant this change was also submitted under the referenced NDA. It appears that the reference document for NDA 19-430, provided as Attachment 1(dated 10/15/2007) in the submission was never entered in the FDA system, and therefore no action letter was issued.

It should be noted that the proposed change (i.e., [redacted] (b) (4) (See Microbiologist's review dated 4/1/2008 under NDA 19-430/S040).

16. Conclusions and Recommendations: The proposed change was approved for other drug products being [redacted] (b) (4) Recommend approval.

17. Name: **Signature:** **Date: 11/6/13**
Mamta Gautam-Basak, Ph.D., Chemist

18. Concurrence:	**Signature:**	**Date:**
Ramesh Raghavachari, Ph.D., Branch Chief **ONDQA/DNDQA III/Branch IX**		

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/s/

MAMTA GAUTAM BASAK
11/08/2013
Recommend approval.

RAMESH RAGHAVACHARI
11/08/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-430/s056

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19430/S-056

CBE SUPPLEMENT – ACKNOWLEDGEMENT

Meridian Medical Technologies, Inc.
Attention: Ellen Kay Losciuto
Manager, Regulatory Affairs
1945 Craig Road
St. Louis, MO 63146

Dear Ms. Losciuto:

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER: 19430

SUPPLEMENT NUMBER: S-056

PRODUCT NAME: EpiPen® and EpiPen® Jr (Epinephrine) Auto-Injector

DATE OF SUBMISSION: May 10, 2013

DATE OF RECEIPT: May 13, 2013

This supplemental application, submitted as a "Changes Being Effected" supplement, proposes (b) (4) parts.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on July 12, 2013, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be November 13, 2013.

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary, Allergy and Rheumatology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

If you have questions, call me, at (301) 796-1926.

Sincerely,

{See appended electronic signature page}

Youbang Liu
Regulatory Project Manager
Division III of New Drug Quality Assessment
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

YOUBANG LIU
06/07/2013