CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-430/S055

Trade Name: EpiPen®

Generic Name: epinephrine

Sponsor: Mylan Specialty L.P.

Approval Date: 9/16/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-430/s055

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	✓
Other Action Letters	
Labeling	
REMS	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	✓
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Other Reviews	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	✓

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-430/s055

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19430/S-055

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) submitted March 22, 2013 and received March 25, 2013, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EpiPen® and EpiPen® Jr (Epinephrine) Auto-Injector.

This "Changes Being Effected" supplemental application proposes to (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.
Acting Branch Chief, Branch IX
Division of New Drug Quality Assessment III
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

RAMESH RAGHAVACHARI
09/16/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

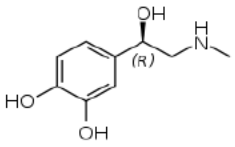
19-430/s055

CHEMISTRY REVIEW(S)

Chemistry Review #1	1. ONDQA (HFD-510)	2. NDA/Suppl. Number 19-430/S-055
3. Name and Address of Applicant Meridian Medical Technologies – a Pfizer Co. Attention: Ellen Kay Losciuto, CQA, RAC 1945 Craig road, St. Louis, MO 63146		4. Date of: Submission 3/22/13 User Fee 9/25/13
5. Name of Drug: Epipen Auto-injector	6. Nonproprietary Name Epinephrine injection	
7. Supplement, CBE-30, Provides for: (b) (4)		8. Amendment(s) 8/13/13
9. Pharmacological Category	10. How Dispensed: Rx	11. Related Documents:
12. Dosage Form Injection	13. Potency(ies):	

15. Drug Name: Epinephrine, 4-[(1R)-1-hydroxy-2-(methylamino)ethyl]benzene-1,2-diol or R-(-)-L-Epinephrine or R-(-)-L-adrenaline

Structure:



16. Comments:

1. Revisions include addition of check boxes on the (b) (4)
2. Specify that (b) (4)

17. Conclusions and Recommendations: Recommend approval.

18. Name: **Signature** **Date**

Review Chemist: Bart Ho, Chemist

Acting Branch Chief
Ramesh Raghavacheri Ph.D.

19430S055 API Meridian

5 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

---

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

/s/

BARTHOLOME C HO
09/10/2013

RAMESH RAGHAVACHARI
09/10/2013

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-430/s055

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

Liu, Youbang

From: Liu, Youbang
Sent: Friday, August 02, 2013 11:20 AM
To: 'kay.losciuto@meridianmt.com'
Subject: Information Request for NDA 19430/S-055

NDA 19430/S-055

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

Dear Ms. Losciuto:

We are reviewing the Chemistry, Manufacturing and Controls sections of your supplemental submission NDA 19430/S-055 dated March 22, 2013 for EpiPen® and EpiPen® Jr (Epinephrine) Auto-Injector.

We have the following comments and information requests. We request a prompt written response in order to continue our evaluation of your submission:

- (b) (4)

Please provide the appropriate information as an amendment to the submission. In addition, a copy of your response submitted by e-mail (youbang.liu@fda.hhs.gov) will expedite the review of your request. In your cover letter refer to the date on which this information was requested.

Please acknowledge the receipt of this email and respond to this information request by August 15, 2013.

Sincerely,

Youbang Liu, Ph.D.
Regulatory Project Manager
Division III, ONDQA/OPS/CDER/FDA
10903 New Hampshire Avenue
Building 21, Room 2525
Silver Spring, MD 20993
Phone: (301) 796-1926

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

/s/

YOUBANG LIU
08/02/2013

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19430/S-055

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-055

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

DATE OF SUBMISSION: March 22, 2013

DATE OF RECEIPT: March 25, 2013

This supplemental application, submitted as a "Changes Being Effected in 30 days" supplement, proposes to (b) (4) (b) (4)

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 May 24, 2013, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be September 25, 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

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

/s/

YOUBANG LIU
04/19/2013