# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

***APPLICATION NUMBER:***

# 20-800/S023

***Trade Name:*** ADRENACLICK®

***Generic Name:*** EPINEPHRINE

***Sponsor:*** Amedra Pharmaceuticals LLC

***Approval Date:*** 9/6/2013

# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 20-800/S023

## CONTENTS

## Reviews / Information Included in this NDA Review.

# CENTER FOR DRUG EVALUATION AND RESEARCH

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# 20-800/S023

# APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20800/S-023

**APPROVAL LETTER**

Amedra Pharmaceuticals LLC
Attention: Michele Roy, RN, MS
Senior Director, Regulatory Affairs
2 Walnut Grove Drive, Suite 190
Horsham, PA 19044-7707

Dear Ms. Roy:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 12, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Twinject/Adrenaclick Auto-Injector (epinephrine) Injection.

This "Prior Approval" supplemental new drug application proposes changes to [(b) (4)] (DMF [(b) (4)]): (1) Change in manufacturing process and process controls; (2) Change in specification for [(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

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/s/

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RAMESH RAGHAVACHARI
09/06/2013

# CENTER FOR DRUG EVALUATION AND RESEARCH

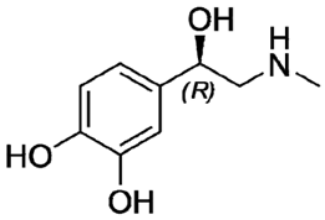
***APPLICATION NUMBER:***

# 20-800/S023

# CHEMISTRY REVIEW(S)

| ***Chemistry Review:# 1*** | **1. Division:** ONDQA-DPARP | **2. NDA Number:** 20800 |
|---|---|---|
| **3. Name and Address of Applicant:**<br>Amedra<br>2 Walnut Grove Drive<br>Suite 190<br>Horsham, PA, 19044-7707 | | **4. Supplement(s):** PAS<br>**Number:**023<br>**Date(s):** 10/12/2013 |
| **5. Name of Drug:** Twinject®/Adrenaclick® auto-injector | | **6. Nonproprietary name:**<br>Epinephrine injection, USP 1:1000 |
| **7. Supplement Provides for**: Changes in the manufacturing and controls of the (b) (4) These changes are described in DMF (b) (4) | | **8. Amendment(s):** |
| **9. Pharmacological Category:** Emergency treatment of severe allergic reactions (Type I) to allergens as well as anaphylaxis to unknown substances (idiopathic anaphylaxis) or exercise-induced anaphylaxis. | **10. How Dispensed:**<br>$R_x$ | **11. Related Documents:** |
| **12. Dosage Form:** sterile injection | **13. Potency:** 0.15 mg, 0.3 mg | |

**14. Chemical Name and Structure:** 1-(3,4-dihydroxyphenyl)-2-(methylamino)ethanol;




**15. Comments:**

- This supplement references to changes in the manufacture of (b) (4) (DMF (b) (4)
- A letter of authorization was provided on 06-Dec-2012
- DMF (b) (4) was reviewed by Erika Englund on 07/15/2013 and found adequate

**16. Conclusion:** This supplement is recommended for approval from CMC perspective

**17. Name:** **Signature:** **Date:**
Erika Englund, Ph.D., Chemist

**18. Concurrence:** **Signature:** **Date:**
Ramesh Raghavachari, Ph.D., Acting Branch Chief, Div., IX, ONDQA

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/s/

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ERIKA E ENGLUND
07/15/2013

RAMESH RAGHAVACHARI
07/15/2013

# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 20-800/S023

# ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20800/S-023

**ACKNOWLEDGEMENT --**
**PRIOR APPROVAL SUPPLEMENT**

Amedra Pharmaceuticals LLC
Attention: Michele Roy, RN, MS
Senior Director, Regulatory Affairs
2 Walnut Grove Drive, Suite 190
Horsham, PA 19044-7707

Dear Ms. Roy:

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

**NDA Number:** 20800

**Supplement number:** S-023

**Name of Drug Product:** Twinject/Adrenaclick Auto-Injector (epinephrine) Injection

**Date of supplement:** June 12, 2013

**Date of receipt:** June 12, 2013

This supplemental application proposes changes to [redacted] (b) (4) (DMF [redacted] (b) (4)): (1) Change in manufacturing process and process controls; (2) Change in specification for [redacted] (b) (4) [redacted]

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 August 11, 2013 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be October 12, 2013.

Please 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

If you have questions, please 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/

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YOUBANG LIU
07/11/2013