CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-414/S-002

Trade Name: Pyridostigmine Bromide Tablets, 30 mg

Generic Name: pyridostigmine bromide

Sponsor: U.S. Army Medical Research and Material Command

Approval Date: January 3, 2014

Indications: For prophylaxis against the lethal effect of Soman nerve agent poisoning.

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APPLICATION NUMBER:

NDA 20-414/S-002

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APPLICATION NUMBER:

NDA 20-414/S-002

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-414/S-002

APPROVAL LETTER

Department of the Army, Office of the Surgeon General
Attention: Robert E. Miller, Ph.D., RAC, Director
U.S. Army Medical Material Development Activity
1430 Veterans Drive
Fort Detrick, MD 21702-5009

Dear Dr. Miller:

Please refer to your Supplemental New Drug Application (sNDA) dated July 3, 2013, received July 5, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pyridostigmine Tablets, USP.

This "Changes Being Effected in 30 days" supplemental new drug application provides for (b) (4) as a new drug product analytical testing site.

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 Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch III, Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

NALLAPERUM CHIDAMBARAM
01/03/2014
for Dr. Hasmukh Patel

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APPLICATION NUMBER:

NDA 20-414/S-002

CHEMISTRY REVIEW(S)

Office of New Drug Quality Assessment
Division of New Drug Quality Assessment I (Branch III)
Review of Chemistry, Manufacturing, and Controls

1. **NDA number: 20414**

2. **Submission(s) Being Reviewed: S002**

Supplement Number	DARRTS SD Number	Submission Date	CDER Stamp Date	Assigned Date	PDUFA Goal Date	Review Date
CBE	155	7/3/13	7/5/13	9/12/13	1/5/13	12/17/13

3. **Proposed Changes: Supplement provides for adding a new analytical testing site, [redacted] (b) (4)**

4. **Review #: 1**

5. **Clinical Review Division:** CDER/ODE1/DNP

6. **Name and Address of Applicant:**
US Army Medical Material Development Activity Attn: MCMR-UMR
1430 Veterans Drive
Fort Detrick, MD 21702
(301) 619-0197

7. **Drug Product:**

Proprietary Name	Nonproprietary Name (USAN) of Drug Substance	Indication	Dosage Form	Strength	Route of Administration
Pyridostigmine Bromide	-	Prophylaxis against lethal effects of Soman nerve agent poisoning	Tablet	30 mg	Oral

Rx or OTC	Special Product?
Rx	-

8. **Chemical name and structure of drug substance:**

[redacted] (b) (4)	**Chemical name:** [redacted] (b) (4) **Molecular formula:** [redacted] (b) (4) **MW:** 261.12

9. Supporting/Relating Document: NA

10. Consults:

- **EES overall recommendation acceptable on 30 August, 2013 from the FDAs Office of Compliance**

11. Summary/Remarks: None

12. Conclusions & Recommendations: Recommend Approval.

13. Comments/Deficiencies to be Conveyed to Applicant: None.

14. Primary Reviewer: Gurpreet Gill-Sangha, Ph.D., CMC reviewer, ONDQA

Secondary Reviewer: Hasmukh Patel, Ph.D., Branch Chief, Branch III, Division of New Drug Quality Assessment I (DNDQA I), ONDQA

(See appended electronic signature page)

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/s/

GURPREET K GILL SANGHA
12/17/2013
N20414-S2-cmc-ggs

HASMUKH B PATEL
12/18/2013