CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-414/S-004

Trade Name: Pyridostigmine Bromide Tablets, 30 mg

Generic Name: pyridostigmine bromide

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

Approval Date: December 23, 2015

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

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APPLICATION NUMBER:

NDA 20-414/S-004

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APPLICATION NUMBER:

NDA 20-414/S-004

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20414/S-004 **APPROVAL LETTER**

Department of the Army
U.S. Army Medical Research and Materiel Command
Attention: Kenneth A. Bertram, MD, Ph.D., Principal Assistant for Acquisition
1430 Veterans Drive
Fort Detrick, MD 21702-5009

Dear Dr. Bertram:

Please refer to your supplemental new drug application dated August 27, 2015, received August 27, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pyridostigmine Bromide Tablets.

We acknowledge receipt of your amendment dated September 3, 2015.

This "Prior Approval" supplemental new drug application notifies the FDA of updates to (b) (4) Drug Master File (b) (4) for Pyridostigmine Bromide 30 mg tablets.

We completed our review of this supplemental new drug application, as amended. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Teshara G. Bouie, Regulatory Business Process Manager, at (301) 796-1649.

Sincerely,

David Lewis, Ph.D., CMC Lead, on behalf of:

Hasmukh Patel, Ph.D.
Division Director (Acting)
Division of Post Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-414/S-004

CHEMISTRY REVIEW(S)

Office of Lifecycle Drug Products
Division of Post-Marketing Activities I
Review of Chemistry, Manufacturing, and Controls

1. **NDA Supplement Number: NDA 20414 / S-004** (b) (4)

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

Submission Number	Type	Submission Date	CDER Stamp Date	Assigned Date	PDUFA Goal Date	Review Date
S-004 (b) (4)	PA	8/27/2015	8/27/2015	9/18/2015	12/27/2015 (b) (4)	12/21/2015

3. **Proposed Changes**: These Prior Approval (b) (4) provide for the updates to the referenced Drug Master File (b) (4).

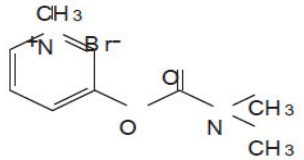
4. **Review #**: 1
5. **Clinical Review Division**: CDER/ODEI/DNP

6. **Name and Address of Applicant**:
The Surgeon General, Department of the Army
U.S. Army Medical Material Development Activity
1430 Veterans Drive
Fort Detrick, MD 21702-5009

7. **Drug Product**:

Drug Name	Dosage Form	Strength	Route of Administration	Rx or OTC	Special Product
Pyridostigmine bromide Tablets, USP	Tablet	30mg Pyridostigmine /tablet	Oral	Rx	No

8. **Chemical Name and Structure of Drug Substance**:

	USAN: Pyridostigmine bromide Chemical name: 3-Hydroxy-1-methylpyridinium bromide dimethylcarbamate Molecular formula: $C_9H_{13}BrN_2O_2$ MW: 261.12

9. **Indication**: Prophylaxis against the lethal effects of soman nerve agent poisoning

10. **Supporting/Relating Documents**: DMF (b) (4)

11. **Consults**: None

12. **Executive Summary**: These Prior Approval (b) (4) S-004 (b) (4) provide for the updates to the Type II DMF No. (b) (4) for Pyridostigmine Bromide 30 mg Tablets. The Letter of Authorization to the applicant dated 8/17/2015 is provided. The DMF updates were reviewed by Lyudmila Soldatova, Ph.D. (Review dated 12/21/2015), and the DMF is found to be Adequate. The alternate drug substance and drug product analytical site, (b) (4) received an Approval recommendation by OPF (refer to Attachment). The inspection was requested in conjunction with referenced DMF (b) (4). Based on the Adequate status of the DMF (b) (4), the Approval is recommended for these (b) (4).

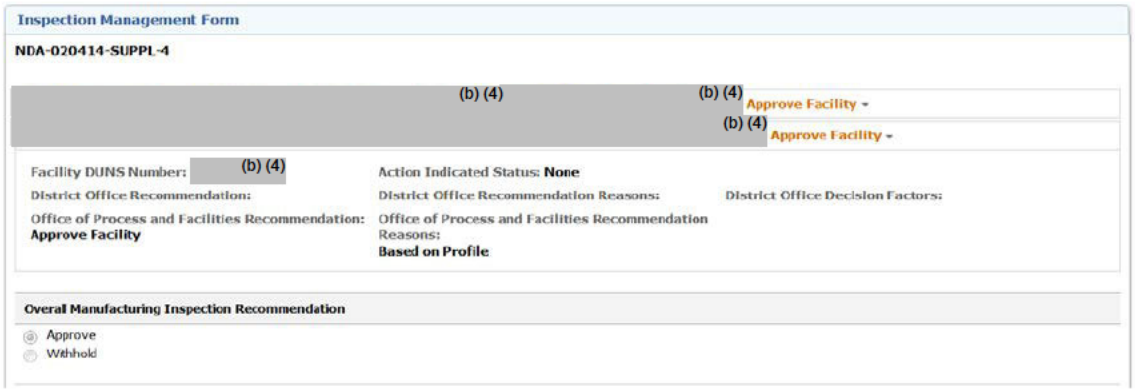
13. **Conclusions & Recommendations**: Recommend Approval based on the Adequate status of the related DMF (b) (4).

14. **Comments/Deficiencies to be Conveyed to Applicant**: None

15. **Primary Reviewer**:
Lyudmila Soldatova, Ph.D., CMC reviewer, Branch #2, Division of Post-Marketing Activities I, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality (OPQ)

16. **Secondary Reviewer**:
Signing for Hasmukh Patel, Ph.D., Branch Chief, Branch #2, Division of Post-Marketing Activities I, Office of Lifecycle Drug Products, OPQ

Attachment


Inspection Management Form

NDA-020414-SUPPL-4

(b) (4) (b) (4) Approve Facility

(b) (4) Approve Facility

Facility DUNS Number: (b) (4)

Action Indicated Status: **None**

District Office Recommendation:

District Office Recommendation Reasons:

District Office Decision Factors:

Office of Process and Facilities Recommendation: **Approve Facility**

Office of Process and Facilities Recommendation Reasons: **Based on Profile**

Overal Manufacturing Inspection Recommendation

Approve

Withhold

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APPLICATION NUMBER:

NDA 20-414/S-004

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

Bouie, Teshara

From: Bouie, Teshara
Sent: Monday, December 21, 2015 10:36 AM
To: 'Matthews, Michael A CTR USARMY MEDCOM USAMMDA (US)'; USARMY Ft Detrick MEDCOM USAMMDA Mailbox USAMRMC REGULATORY AFFAIRS
Subject: RE: NDA 20414 Pyridostigmine Bromide (UNCLASSIFIED)

Thanks for clarifying. We will change the September submission to an amendment to supplement S-004.

Teshara G. Bouie

-----Original Message-----
From: Matthews, Michael A CTR USARMY MEDCOM USAMMDA (US) [mailto:michael.a.matthews8.ctr@mail.mil]
Sent: Monday, December 21, 2015 10:34 AM
To: Bouie, Teshara; USARMY Ft Detrick MEDCOM USAMMDA Mailbox USAMRMC REGULATORY AFFAIRS
Subject: RE: NDA 20414 Pyridostigmine Bromide (UNCLASSIFIED)

Classification: UNCLASSIFIED
Caveats: NONE

Hi Teshara,

The two submissions are the same.

When we submitted this the first time (August 27, 2015, SN0054), the signed FDA Form 354h was incorrect. (b) (4) with the correct signed 356h form.

I hope that clarifies these submissions. Please let me know if you have any additional questions.

Thank you,
Michael

-----Original Message-----
From: Bouie, Teshara [mailto:Teshara.Bouie@fda.hhs.gov]
Sent: Monday, December 21, 2015 10:25 AM
To: USARMY Ft Detrick MEDCOM USAMMDA Mailbox USAMRMC REGULATORY AFFAIRS; Matthews, Michael A CTR USARMY MEDCOM USAMMDA (US)
Subject: [Non-DoD Source] NDA 20414 Pyridostigmine Bromide
Importance: High

Hi Michael,

We received S-004 on August 27, 2015 (b) (4) The (b) (4) appear to be the same. Per the cover letters, (b) (4) provide for updates to drug master file (DMF) (b) (4). Please clarify any differences between the (b) (4).

Thanks,

Teshara G. Bouie, MSA, OTR/L

CDR, United States Public Health Service

Regulatory Business Process Manager

FDA/CDER/OPQ/OPRO

Phone (301) 796-1649

Fax (301) 796-9749

Classification: UNCLASSIFIED
Caveats: NONE

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

/s/

TESHARA G BOUIE
12/22/2015