CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-414/S-003

Trade Name: Pyridostigmine Bromide Tablets, 30 mg

Generic Name: pyridostigmine bromide

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

Approval Date: September 30, 2014

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

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APPLICATION NUMBER:

NDA 20-414/S-003

CONTENTS

Reviews / Information Included in this NDA Review.

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

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APPLICATION NUMBER:

NDA 20-414/S-003

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-414/S-003

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 (sNDA) dated April 3, 2014, received April 4, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pyridostigmine Bromide Tablets.

We acknowledge receipt of your amendment dated September 10, 2014.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of a new drug product manufacturing site, (b) (4)

We have completed our review of this supplemental new drug application, as amended. 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/

HASMUKH B PATEL
09/30/2014

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-414/S-003

CHEMISTRY REVIEW(S)

Review of Chemistry, Manufacturing, and Controls

Clinical Review Division: Division of Psychiatry Products

NDA #:	CHEM. REVIEW #:	REVIEW DATE:
20-414	1	09/30/14

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE	DUE DATE
N 20414/S-003 (CBE)	04/03/14	04/04/14	04/28/14	10/04/14

NAME & 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

DRUG PRODUCT NAME

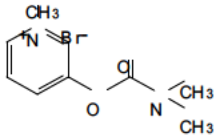
Proprietary: Pyridostigmine Bromide Tablets
Nonproprietary/USAN: Pyridostigmine Bromide

PHARMACOLOGICAL CATEGORY/INDICATION: For prophylaxis against the lethal effects of soman nerve agent poisoning

DOSAGE FORM: Tablet
STRENGTHS: 30mg Pyridostigmine/tablet
ROUTE OF ADMINISTRATION: Oral
DISPENSED: Rx
SPECIAL PRODUCTS: ☐ Yes ☒ No (If yes, fill out the form for special products and deliver to TIA through team leader for data entry)

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL. WT:

Chemical Name: 3-Hydroxy-1-methylpyridinium bromide dimethylcarbamate
Molecular Wt.: 261.12
Molecular Formula: $C_9H_{13}BrN_2O_2$



SUPPORTING DOCUMENTS: Amendment (BC) dated 10-SEP-2014
RELATED DOCUMENTS: DMF [redacted] Review dated 29-SEP-2014
REMARKS/COMMENTS:

This Changes-being-Effected supplement requests approval to add an alternate drug product manufacturing site. The supplement also proposes [redacted] The drug substance and drug product [redacted]. Analytical methods used for [redacted]

The proposed site will use an updated Type II Drug Product DMF, which has been reviewed and found to be Adequate. All [redacted] are appropriate and acceptable. The changes to the [redacted] have been adequately described and are well-documented.

The District Office recommended that the site is acceptable based on profile. The overall recommendation of Acceptable was made by the Office of Compliance.

CONCLUSIONS & RECOMMENDATIONS: The CMC information presented in the submission to support the requested change is acceptable. The supplement is recommended for APPROVAL.

cc: Orig. NDA 20-414
DMIHP/Division File
DMIHP/CSO/T.Bouie

filename: n20414s.003.doc

Allan Fenselau, Ph.D., Review Chemist

DRAFT SUPPLEMENT LETTER

There are no CMC–specific deficiencies.

4 page(s) has been Withheld as b4 (CCI/TS) immediately following this page

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/s/

ALLAN H FENSELAU
09/30/2014

NALLAPERUM CHIDAMBARAM
09/30/2014
for Dr. Hasmukh Patel

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-414/S-003

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-414/S-003 **CBE-30 SUPPLEMENT**

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:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Pyridostigmine Bromide Tablets

NDA Number: 20-414

Supplement number: S-003

Date of supplement: April 3, 2014

Date of receipt: April 4, 2014

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 days," proposes the addition of a new drug product manufacturing site, (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 June 3, 2014 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be October 4, 2014.

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 Neurology Products
5901-B Ammendale Road

Beltsville, MD 20705-1266

If you have questions, call me, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

Teshara G. Bouie, MSA, OTR/L
CDR, USPHS, Regulatory Health Project Manager
Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

TESHARA G BOUIE
05/02/2014