NDA 020414/S-011

CORRECTED APPROVAL LETTER

The Surgeon General, Department of the Army
Attention: Emily Badraslioglu, MS, PMP, RAC
Sponsor's Representative
1541 Porter Street
Fort Detrick, MD 21702

Dear Ms. Badraslioglu:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 24, 2024, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pyridostigmine Bromide tablet.

We also refer to our approval letter dated October 4, 2024, which contained the following error: Incorrect "For" address on page seventeen of the Physician Insert.

This corrected action letter incorporates the correction of the error. The effective action date will remain October 4, 2024, the date of the original letter.

This Prior Approval supplemental new drug application provides for extension of the expiration period; once the drug product in blister packaging has been removed from the foil overwrap, labeled, and issued to military personnel; from 3 months to 14 months.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on **September 13, 2024, (blister pack foil backing label and carton shipper label)** and **September 25, 2024, (aluminum pouch foil overwrap label and blister pack sleeve label)**, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020414/S-011.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Erica Keafer, Regulatory Business Process Manager, at (301) 796 – 1435 or erica.keafer@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Supervisor

For:
Gurpreet Gill-Sangha, Ph.D.
Supervisor
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DAVID B LEWIS
10/09/2024 11:35:36 AM
concur; address in the USPI is corrected.