NDA 021175/S-047

SUPPLEMENT APPROVAL

The Surgeon General, Department of the Army
U.S. Army Medical Research and Development Command
Attention: Mark Paxton, JD
1430 Veterans Drive
Fort Detrick, MD 21702-5009

Dear Mr. Paxton:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 29, 2021, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ATNAA (atropine/pralidoxime chloride) Auto- Injector.

This "Changes Being Effected" supplemental new drug application provides for responses to the FDA's requested revisions and/or comments to the ATNAA labeling noted in the CBE 0 supplement request letter dated October 18, 2021to include:

1. The quantitative amounts of ingredients in the citrate buffer system (citric acid monohydrate and sodium citrate dihydrate).
2. Revision in Section 16 of PI and container labels to include equivalency statements to indicate exact amount of pralidoxime chloride corresponding to pralidoxime.
3. Revision in container labels to include "Manufactured by" and "Distributed by".
4. Revise the expression of strength on the container label to include the total volume to read "2.1 mg/0.7 mL" and "600 mg/2 mL" for atropine and pralidoxime chloride, respectively.
5. A statement on the container labeling to indicate the key element that one activation sequentially delivers the API from both chambers.

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 carton and container labels submitted on May 24, 2022, 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 021175/S-047.**" Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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

If you have any questions, call Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

{See appended electronic signature page}

For
Gurpreet Gill-Sangha, Ph.D.
Branch Chief, Branch 3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling
Carton and Container Labeling

Rohit Kolhatkar

Digitally signed by Rohit Kolhatkar
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