NDA 205029/S-012

APPROVAL LETTER

BPI Labs LLC
Attention: Ravi Kumar Tirlangi
Associate Director - Regulatory Affairs
12393 Belcher Rd S
Suite 450
Largo, FL 33773

Dear Ravi Kumar Tirlangi:

Please refer to your Supplemental New Drug Application (sNDA) dated March 14, 2023, received September 27, 2023, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Epinephrine Injection USP, 1 mg/mL.

We acknowledge receipt of your amendment dated September 27, 2023, which constituted a complete response to our June 29, 2023, action letter.

This Prior Approval supplemental new drug application provides for:

- Addition of a new single-dose 1 mL vial presentation of Epinephrine Injection, USP 1 mg/mL.
- Withdrawal of (b) (4)

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

We acknowledge your June 1, 2023, submission containing final printed carton and container labeling.

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 Grafton Adams at grafton.adams@fda.hhs.gov .

Sincerely,

{See appended electronic signature page}

Joyce Crich Ph.D.
On behalf of
Gurpreet Gill-Sangha, Ph.D.
Supervisor, Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality

Enclosure(s):
Content of Labeling
Carton and Container Labeling

Joyce Crich

Digitally signed by Joyce Crich
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