DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20800/S-035

SUPPLEMENT APPROVAL

Impax Laboratories, LLC
30831 Huntwood Avenue
Haywood, CA 94544

Attention: Elaine Ogunbiyi
Director, Regulatory Affairs

Dear Ms. Ogunbiyi:

Please refer to your Supplemental New Drug Application (sNDA) dated June 8, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Twinject/Adrenaclick/authorized generic (epinephrine injection, USP) Auto-Injector, 0.15 mg and 0.30 mg.

This Changes Being Effected supplemental new drug application was submitted in response to the Agency's supplement request, dated May 11, 2018, to add language for cardiomyopathy to the adverse reaction sections of the prescribing information for all the products.

Regarding your amendments dated May 20, 2016 and July 10, 2018, we have the following comments. Since you are not currently marketing Twinject or Adrenaclick, you are not required to update the manufacturing information for these products at this time.

There is also no need to convert the Twinject package insert to the PLR format, at this time. If in the future, you plan to market either Twinject or Adrenaclick, the manufacturing information in the labeling will be required however, it can be included in the Annual Reports for these products. In addition, PLR conversion will be required for Twinject if marketing resumes.

Since the approval for Twinject, Adrenaclick, and the authorized generic are under NDA 20800, Twinject cannot be withdrawn; to withdraw one product is to withdraw all products under the NDA. Alternately, you may remove the NDC number and have the listing in the Orange Book revised.

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 text.

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, text for the patient package insert and text for the instructions for use 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 from 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Carol F. Hill, Senior Regulatory Health Project Manager, at 301-796-1226.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Acting Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of 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/

SALLY M SEYMOUR
08/29/2018