



NDA 017007/S-039

SUPPLEMENT APPROVAL

West-Ward Pharmaceuticals International Limited (WWPIL)
c/o West-Ward Pharmaceuticals Corp.
Attention: Michelle P. Dugan
US Representative for WWPIL
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Dear Ms. Dugan:

Please refer to your Supplemental New Drug Application (sNDA) dated January 19, 2018, received January 19, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for heparin sodium injection, USP; Heparin Lock Flush Solution, USP; 1000 units per mL, 2500 units per mL, 5,000 units per 0.5 mL, 5,000 units per mL, 7,500 units per mL, 10,000 units per mL, and 20,000 units per mL IV injection or infusion, or subcutaneous injection.

We also refer to our approval letter dated March 27, 2018 which contained the following error: incorrect list of available strengths for heparin sodium.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 27, 2018, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for clarifications to the indications section, as well as updates to the precautions, and pediatric dosage and administration sections of the label.

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 package insert 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 Beatrice Kallungal, Regulatory Project Manager,
at (301) 796-9304.

Sincerely,

{See appended electronic signature page}

Barry Miller, MS, CRNP
Acting Deputy Director for Safety
Division of Hematology Products
Office of Hematology Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BARRY W MILLER
03/27/2018