DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 209463-S005

SUPPLEMENT APPROVAL

Exela Pharma Sciences LLC
C/O West-Ward Pharmaceuticals Corp.
Attention: J. Barton Kalis
Sr. Director, Regulatory Affairs
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

Dear Mr. Kalis:

Please refer to your Supplemental New Drug Application (sNDA) dated August 20, 2018, received submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pantoprazole Sodium for Injection, 40 mg per vial.

We also refer to our letter dated June 7, 2018 notifying you of the class safety labeling change under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Pantoprazole Sodium. This information pertains to the risk of Fundic Gland Polyps (FGPs) among patients using PPIs for more than one year.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the following minor editorial revisions :

Table of Contents

- Indented text of subsection headings that wrapped around to a second line
- Removed underline from "Methotrexate" in the text for Section 5.11 Concomitant Use of Pantoprazole Sodium for Injection with Methotrexate
- Indented Section 5.12 Fundic Gland Polyps to align with other subsections

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 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).

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 Brian Strongin, Regulatory Project Manager, at (301) 796-1008.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
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/

JOYCE A KORVICK
10/10/2018