NDA 018832/S-056, S-058, S-061
NDA 018877/S-063, S-065, S-068

SUPPLEMENT APPROVAL

Watson Laboratories, Inc.
c/o Teva Pharmaceuticals USA, Inc.
Attention: Janet Vaughn
Vice President, Regulatory Affairs, NA, Generics
400 Interpace Parkway, Building A
Parsippany, NJ 07054

Dear Janet Vaughn:

Please refer to your supplemental new drug applications (NDAs), and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application Number	Supplement Number	Drug Name	Submitted and Received
018832	056	Allopurinol tablets 100 mg	February 25, 2019
	058		March 12, 2020
	061		November 3, 2023
018877	063	Allopurinol tablets 300 mg	February 25, 2019
	065		March 12, 2020
	068		November 3, 2023

These supplemental NDAs provide for, respectively:

- updates to the Package Insert to align with changes approved for the reference product, Zyloprim, on December 3, 2018, including addition of the risk of Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) in the WARNINGS section,
- updates to the WARNINGS section with the risk of allopurinol-induced severe cutaneous adverse reactions associated with the presence of the HLA-B*5801 allele, and
- labeling revisions in response to the Agency's letter dated October 05, 2023, requesting Physician Labeling Rule (PLR) conversion (including compliance with the Pregnancy and Lactation Labeling Rule) in accordance with 21 CFR 201.57.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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 FDA.gov.[1] 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Because none of these criteria apply to your applications, 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 Saharat Patanavanich, Regulatory Project Manager, at (240) 402-0139.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, MD, MPH
Deputy Director
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling - Prescribing Information

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/

OZLEM A BELEN
04/03/2024 12:38:00 PM