



NDA 208843/S-005

TENTATIVE APPROVAL

Theravia SAS
c/o DS InPharmatics subsidiary of PLG-group
Attention: Catherine Bernard, PhD
US Agent and Regulatory Affairs Consultant
PO Box 532
Harleysville, PA 19438

Dear Dr. Bernard:

Please refer to your supplemental new drug application (sNDA) dated and received March 22, 2024, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for (FD&C Act) for Siklos (hydroxyurea) tablets.

This supplemental new drug application proposes the use of Siklos (hydroxyurea) tablets (b) (4)

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105(a); therefore, this application is not approved and will not be approved until FDA issues an approval letter after any necessary additional review of the application. Enclosed are the tentatively approved labeling (Prescribing Information, (b) (4) carton and container labeling). This tentative approval determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

Final approval of your application is subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application may not be granted before the period has expired.

Under section 527(a) of the FD&C Act, orphan-drug exclusivity prevents FDA from approving or licensing the same drug for the same use or indication for a person who is not the holder of such approved application or of such license until the expiration of seven years from the date of approval or licensure. Nova Laboratories' product, Xromi (hydroxyurea) oral solution has orphan-drug exclusivity, which blocks final approval of

sNDA 208843/S-005 for Siklos (hydroxyurea) film-coated tablets until Xromi's orphan-drug exclusivity expires on April 4, 2031.

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as “**REQUEST FOR FINAL APPROVAL**”. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this supplemental NDA is not approved, and the use of the enclosed tentatively approved labeling is not permitted for marketing the drug product. If you believe that there are grounds for issuing the final approval letter before the expiration of the exclusivity protection, you should amend your application accordingly.

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.

We note that if this application is ultimately approved, you will need to meet these requirements.

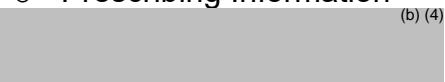
If you have any questions, call Bijal Patel, Regulatory Project Manager, at 240-402-4829 or at bijal.patel1@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tanya Wroblewski, MD
Deputy Division Director
Division of Nonmalignant Hematology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES: (tentatively approved)

- Content of Labeling
 - Prescribing Information
 -  (b) (4)
- Carton and Container Labeling

31 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/

TANYA M WROBLEWSKI
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