CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

218139Orig1s000

STATISTICAL REVIEW(S)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW MEMORANDUM

CLINICAL STUDIES

NDA/BLA #:	218139
Drug Name:	Terazosin oral solution, 1 mg/mL (proposed trade name: TEZRULY)
Indication(s):	Treatment of symptomatic benign prostatic hyperplasia (BPH) and hypertension
Applicant:	Novitium Pharma LLC
Date(s):	Submitted: 9/29/2023 PDUFA: 7/29/2024
Review Priority:	Standard
Biometrics Division:	Division of Biometrics IV
Statistical Reviewer:	Yun Tang, Ph.D.
Concurring Reviewers:	Solomon Chefo, Ph.D., Team Leader
Medical Division:	Division of Urology, Obstetrics and Gynecology (DUOG)
Clinical Team:	Marjorie Dannis, M.D., Clinical reviewer Mark Hirsch, M.D., Clinical team leader
Project Manager:	Sydney Tran

Keywords: NDA review

MEMORANDUM

The Applicant submitted a New Drug Application (NDA) for their terazosin oral solution via 505(b)(2) pathway for the treatment of BPH and hypertension. To support this 505(b)(2) NDA, the Applicant relies on findings from NDA 020347 (Hytrin, terazosin capsules, 1 mg, by Abbott Laboratories) as the listed drug. The Applicant conducted the following two comparative bioavailability studies to establish a clinical bridge with Hytrin:

- A Single-Dose, Open Label, Randomized, Balanced, Three-Period, Two-Treatment, Three-Sequence, Three-Way Crossover Study in Healthy Human Adult Subjects to Assess Oral Bioavailability and to Assess the Effect of Food on Test Formulation of Terazosin Hydrochloride Oral Solution 1 mg/mL Under Fed (Treatment A) and Fasted (Treatment B)Conditions with a Reference Formulation of Terazosin Capsules USP 1 mg (Treatment C) Under Fasted Conditions (Study #: TERA-21-077)

- An Open-Label, Balanced, Randomized, Single-Dose, Two-Treatment, Two-Sequence, Two-Period, Two-Way Crossover, Oral Bioavailability Study Comparing Terazosin Hydrochloride Oral Solution 1 mg/mL (Test Product) with that of Terazosin Capsules USP 1 mg (Reference Product) in Healthy, Adult Human Subjects Under Fed Conditions (TERA-23-003)

No new clinical efficacy data were submitted in this NDA to support the approval of the proposed Terazosin oral solution. Therefore, statistical review of NDA 218139 is not necessary. The decision on approvability of the proposed drug product is deferred to the DUOG.

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/

YUN TANG
06/21/2024 12:31:09 PM

SOLOMON CHEFO
06/21/2024 01:38:31 PM