



5671 Peachtree Dunwoody Road, STE 550
Atlanta, GA 30342

T: 404-600-6343
F: 678-927-9031

September 19, 2025

Aliza M. Thompson, MD, MS
Director, Division of Cardiology and Nephrology
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Division of Cardiology and Nephrology
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: **PREXXARTAN™ (Valsartan) Oral Solution, 4mg/mL , NDA # 209139 – RESPONSE TO PREA NON-COMPLIANCE LETTER**

Dear Dr. Thompson:

Thank you for your notification regarding non-compliance with PREA, dated August 26, 2025.

We acknowledge that our deferral extension request, submitted on April 14, 2025, was denied, and that the subsequent request, submitted on July 22, 2025, was granted on September 9, 2025. We also recognize that these requests occurred after the revised Final Report Submission deadline of June 2025.

In light of the approved extension through June 2026, we respectfully request that the PREA Non-Compliance letter not be published under Section 505B(d)(1). We are committed to submitting the Final Study Report of **PMR # 3319-3** well before this new deadline and are taking all necessary steps to prevent any further delays.

We sincerely appreciate your understanding and continued collaboration as we work towards timely completion of our obligations. Please do not hesitate to contact us if further information or clarification is needed.

Thank you for your consideration.

A handwritten signature in black ink, appearing to read 'Bobby V. Khan'.

Sincerely,
Bobby V. Khan, M.D., Ph.D.
Executive Director, Carmel Biosciences
Telephone: 404-600-6343
Email: bkhan@carmelbio.com

