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RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

June 7, 2024

Rigoberto Roca, M.D.
Director, Division of Anesthesiology,
Addiction Medicine, and Pain Medicine
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Control Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

Attn: Giang T. Le, PharmD, Regulatory Health Project Manager

Re: NDA 209229 – LUCEMYRA (lofexidine)
Sequence Number 0261
Response to PREA Non-Compliance Letter dated April 24, 2024 and Deferral Extension Request for PREA PMRs 3391-2 and 3391-4

Dear Dr. Roca:

In response to the Pediatric Equity Act (PREA) Non-Compliance Letter for Postmarketing Requirement (PMR) 3391-2 dated April 24, 2024, USWM, LLC herein submits for the Agency's Review and Consideration a Request for Deferral Extension for two clinical PREA PMRs: PMR 3391-2 and PMR 3391-4. The Request for Deferral Extension includes the reasons for delay in submitting the final report for the clinical trial intended to fulfill PMR 3391-2 (b) (4) as well as a date by which the Sponsor expects to submit the final report for that trial.

USWM requests that all information in this file be treated as confidential to the extent possible in accordance with 21 CFR 20.61 and that no information from this file may be provided to any unauthorized persons without our written consent.

Should further assistance or clarification be required, please feel free to contact me at your convenience via phone at (614) 352-3943 or email RegulatoryAffairs@USWorldmeds.com.

Sincerely,

Adam Reuther
Director, Regulatory Affairs
USWM, LLC

Electronic Submission Technical Information

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway.

Anti-Virus Program	Microsoft Defender Antivirus
Program Version	1.413.X
Virus Definition Date	June 7, 2024

The technical point of contact for this submission is:

Name	Kay Moles
Phone Number	859-608-3094
Email Address	RegulatoryAffairs@USWorldmeds.com