Guerbet

RESPONSE TO PREA NON-COMPLIANCE LETTER

Guerbet LLC

821 Alexander Rd - Suite 204
Princeton, NJ 08540
Tel: 812-333-0059
Fax: 609-919-0495
www.guerbet-us.com

August 15, 2016

Libero Marzella, MD, PhD, Director
FDA/CDER/ODE IV/ DMIP
5901-B Ammendale Road
Beltsville, MD 20705-1266

Attn: Su-Lin Sun, PharmD, Senior Regulatory Project Manager, DMIP

Re: NDA 204781 – DOTAREM® (gadoterate meglumine) Injection
Sequence 0040
Response to PREA Non-Compliance Letter

Dear Dr. Marzella,

Reference is made to New Drug Application 204781 for Dotarem® (gadoterate meglumine) Injection, approved on March 20, 2013 and to IND 65041, specifically, SN 0338 and SN 0352. Reference is also made to our submission of Required Pediatric Assessments submitted on June 3, 2016 (b) (4) PREA non-compliance letter received July 7, 2016 and subsequent email correspondence with the Agency in response to the non-compliance letter. This submission includes our formal written response to the PREA non-compliance letter.

Guerbet submitted a Phase IV clinical study report for protocol DGD-44-063, entitled "Dotarem® Pharmacokinetics, Safety and Efficacy Study in Pediatric Subjects Aged < 2 years (Term Newborn Infants to Toddlers 23 Months of Age Inclusive)," in accordance with and in response to timeline requirements established in our March 20, 2013 NDA 204781 approval letter. As outlined in our approval letter, 'Final Report Submission' was due in June of 2016. As referenced here, Guerbet submitted the clinical study report on June 3, 2016.

Guerbet has always intended and will fully comply with the labeling supplement requirement of the Act. As noted in our June 3, 2016 submission, Guerbet's intent was to submit the proposed label change in a forthcoming supplement while working to insure that the clinical study report was submitted in compliance with the agreed upon and required timeline.

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At this time, Guerbet wishes to confirm with the Agency that the required labeling supplement will be submitted no later than October 31, 2016. No deferral is requested as the assessments have been completed. (b) (4)

(b) (4)

Should you have any questions or comments, please contact me by phone at 812-333-0059, or by e-mail to alice.lorenzo@guerbet-group.com.

Sincerely,

Alice Lorenzo

Alice Lorenzo, MJ, MBe, RAC
Compliance Officer, Head of North American Regulatory and Quality

cc: Ira Krefting, MD, Deputy Director for Safety
Rene Tyson, Safety Regulatory Project Manager

Cross Reference IND 65041