



Meridian Medical Technologies, Inc.  
1945 Craig Road  
St. Louis, MO 63146

July 1, 2015

William Dunn, MD, Acting Director  
Division of Neurology Drug Products  
Food and Drug Administration  
Center for Drug Evaluation and Research  
5901-B Ammendale Road  
Beltsville, Maryland 20705-1266

**Re: NDA 021983, DuoDote (atropine and pralidoxime chloride injection) Auto-Injector  
Postmarketing Requirement Set No. 1300-1  
RESPONSE TO PREA NON-COMPLIANCE LETTER dated May 20, 2015**

Dear Dr. Dunn:

Reference is made to NDA 021983 DuoDote (atropine and pralidoxime chloride injection) Auto-Injector, approved on 28 September 2006, and to Postmarketing Requirement Set No. 1300-1. Reference is also made to FDA's Notification of Non-Compliance with PREA Letter to NDA 021983 on May 20, 2015.

Meridian Medical Technologies Inc. (Meridian), a Pfizer Company, requested a deferral extension dated December 20, 2012, which was granted by FDA on July 9, 2013 establishing the final report submission date of March 30, 2015. Per recommendations provided by FDA in the July 2013 response, Meridian began [REDACTED] (b) (4) In two separate submissions, dated December 22, 2014 and March 26, 2015, Meridian outlined the rationale for why submission of the required pediatric assessment under this PMR by March 30, 2015 was not possible, along with a proposed timeline and respective rationale for submission of the pediatric assessment. These submissions were inclusive of requests for a deferral extension of the PREA commitment, which were denied by FDA in separate letters dated February 6, 2015 and May 7, 2015.

Meridian is fully committed to fulfilling its postmarketing obligations under PREA and submission of the pediatric assessment [REDACTED] (b) (4)

(b) (4)

Should you have any questions regarding this response, please contact me by phone at (314) 682-3297 or by email at [pamela.uetrecht@meridianmt.com](mailto:pamela.uetrecht@meridianmt.com).

Sincerely,

A handwritten signature in black ink, appearing to read "Pamela Uetrecht". The signature is fluid and cursive, with the first name being more prominent.

Pamela Uetrecht  
Regulatory Strategist  
Meridian Medical Technologies, Inc., a Pfizer Company

Cc: FDA Pediatric and Maternal Health Staff (PMHS)