



May 31, 2016

**CROSS REFERENCE COPY TO IND 13546**

Food and Drug Administration  
Center for Biologics Evaluation and Research  
Document Control Center  
10903 New Hampshire Ave  
WO71 - G112  
Silver Spring, MD 20993-0002

Re: **RESPONSE TO PREA NON-COMPLIANCE LETTER**  
BLA: 103738/5156  
IND: 13546  
Manufacturer: SmartPractice Denmark ApS  
License #: 1888

Dear Lt. Valenti;

In response to your May 11, 2016 Notification of Non-Compliance with PREA letter, we herewith are informing the Agency that the Final Report for Protocol SP 12 7NEW 401: Clinical Evaluation of T.R.U.E. TEST® Panel 3.2 in Children and Adolescents (PREA II) has been completed and submitted under separate cover.

In accordance with your instructions, we have submitted a cross-reference copy of this letter to IND 13546 simultaneously.

We apologize for the delay in completion of this Final Report. Please let us know if you require additional information.

Sincerely,

**(b) (6), (b) (7)(E)**

Kim M. Sullivan  
U.S. Agent for SmartPractice Denmark ApS  
(602) 225-9090 X7274  
encl: Forms 356h, 2567 (3 copies)  
cc: IND 13546 (cross-reference letter)