DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NOTIFICATION OF NON-COMPLIANCE WITH PREA

Our STN: BL **103738/5156**

SmartPractice Denmark ApS
Attention: Kim M. Sullivan
Vice President, Regulatory
3400 East McDowell Road
Phoenix, AZ 85008

May 11, 2016

Dear Ms. Sullivan:

Please refer to your Supplemental Biologic License Application (BLS) submitted under section 351 of the Public Health Service Act for Thin-Layer Rapid Use Epicutaneous Patch Test (T.R.U.E. TEST).

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your final clinical study report for PMR #1 cited in BLS 103738/5074 approval letter dated February 29, 2012.

Under the provisions of title V, section 505, of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and date(s) by which you expect to submit the final clinical study report and efficacy supplement to request the use of T.R.U.E. TEST in children 6 through 17 years of age. On December 30, 2013, we granted a deferral extension until December 31, 2015. We note that you requested a second deferral extension on November 10, 2015; however, in our December 21, 2015, letter, we determined that your request did not qualify for an extension because you did not provide an explanation for the deferral extension request and your request was not submitted at least 90 days prior to the deferral expiration.

In accordance with FDASIA, FDA will post this letter and your response on the website located at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm448393.htm with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please submit your response to this letter within 45 days to STN BLS 103738/5156. Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER**." To facilitate our review, submit a cross-reference letter to the IND to which your protocol has been submitted.

If you have any questions, call CDR Elizabeth J. Valenti, MPH, RAC (U.S.), Regulatory Project Manager, at (301) 796-2640.

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccine and
Related Product Application
Office of Vaccines and
Research and Review
Center for Biologics
Evaluation and Research