



RESUBMISSION ACKNOWLEDGEMENT

Our STN: BL 125579/0

SmartPractice Denmark ApS
Attention: Kim Sullivan
3400 East McDowell Road
Phoenix, AZ 85008

September 21, 2015

Dear Ms. Sullivan:

We have received your August 25, 2015, resubmission to your biologics license application for Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test on August 27, 2015.

We consider this a complete response to our action letter. Therefore, the goal date is February 26, 2016.

If you have any questions regarding the above, please contact the Regulatory Project Manager, Ms. Christina Houck, at 301-796-2640.

Sincerely yours,

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