



**BLA ASSIGNMENT LETTER**

SmartPractice Denmark AsP  
Attention: Kim M. Sullivan  
3400 East McDowell Road  
Phoenix, AZ 85008

December 2, 2014

Dear Ms. Sullivan:

We have received your biologics license application (BLA) submitted under section 351 of the Public Health Service Act for the following biological product:

**Our Submission Tracking Number (STN):** BL 125579/0

**Biological Product:** Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test

**Indication:** For use as an aid in the diagnosis of allergic contact dermatitis in persons 18 years of age and older whose history suggests sensitivity to one or more of the five substance included on the Rubber Panel T.R.U.E. TEST.

**Date of Supplement Complete Response:** August 19, 2014

**Date of Receipt:** August 21, 2014

**Goal Date:** February 20, 2015

**US License Number:** 1888

As previously communicated in a telecon on June 7, 2013, between you and CDR Elizabeth Valenti, your PAS was converted to a new BLA. The new STN for your Rubber Panel T.R.U.E. TEST submission is 125579/0.

Please submit all future correspondence, supporting data, or labeling relating to this supplement, citing the above STN number. Send all correspondence to the following address:

Office of Vaccines Research and Review  
Food and Drug Administration  
Center for Biologics Evaluation and Research  
Document Control Center  
10903 New Hampshire Ave  
71, G112  
Silver Spring, MD 20993-0002

Applicants who sent applications via the Food and Drug Administration Electronic Submissions Gateway (ESG) should continue to use those procedures. The ESG is an Agency-wide solution for accepting electronic regulatory submissions that enables the secure submission of regulatory information for review. Instructions for setting up an ESG account can be found at <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>

CBER strongly encourages the use of secure email. Secure email makes use of encryption during transmission and the messages are decrypted upon receipt using the certificate. To establish secure email, please follow the instructions in *SOPP 8119: Use of Email for Regulatory Communications*, Appendix 1 or Appendix 2.

CBER may communicate with you via non-secure email if you provide written authorization to do so. Authorization is file specific; please submit new authorization for each file and/or submission you hold with CBER.

Please note that CBER will only use email in place of telephone communications for general discussions, to relay regulatory issues and to request information. CBER will not provide copies of letters or meeting minutes by email and will not usually accept regulatory submissions via email.

If you have any questions, please contact LCDR Elizabeth Valenti, Regulatory Project Manager, at (301) 796-2640.

Sincerely yours,

Paul G. Richman, Ph.D.  
Chief  
Regulatory Review Branch 1  
Division of Vaccines and  
Related Products Applications  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research