



**SUPPLEMENT APPROVAL  
PMR FULFILLED**

OUR STN: BL 103738/5162

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

August 25, 2017

Dear Ms. Sullivan:

We have approved your request dated October 26, 2016, to supplement your Biologics License Application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Thin-layer Rapid Use Epicutaneous Patch Test (T.R.U.E. TEST), to use as an aid in the diagnosis of allergic contact dermatitis in persons 6 years of age and older whose history suggests sensitivity to one or more of the 35 substances included on the T.R.U.E. TEST panels.

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT 01797562.

**LABELING**

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft package insert labeling submitted in your communication of August 24, 2017, and the draft carton and container labeling submitted under amendment 5003, dated February 22, 2017.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. All final labeling should be submitted as Product Correspondence to BLA 103738 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system, (eLIST) as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

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

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

This submission fulfills your postmarketing requirement #1 identified in the February 29, 2012 approval letter for STN 103738/5074 for Thin-layer Rapid Use Epicutaneous Patch Test (T.R.U.E. TEST). The requirement addressed in this submission is as follows:

1. Deferred pediatric study under PREA to evaluate T.R.U.E. TEST and the seven new allergens in pediatric patients ages six to seventeen.

Final Protocol Submission: June 2012

Study Completion Date: September 2013

Final Report Submission: December 31, 2013

## **PEDIATRIC REQUIREMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

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