Our STN: BL 125579/0 **BLA APPROVAL**

SmartPractice Denmark ApS
Attention: Kim M. Sullivan March 3, 2017
SmartPractice Denmark ApS
Vice President, Research & Regulatory
3400 East McDowell Road
Phoenix, AZ 85008

Dear Ms. Sullivan:

Please refer to your Biologics License Application (BLA) for Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test dated January 5, 2006, received January 9, 2006, submitted under section 351(a) of the Public Health Service Act (PHS Act).

We have approved your BLA for Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test effective this date. SmartPractice Denmark ApS is hereby authorized to introduce or deliver for introduction into interstate commerce, Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test under their existing Department of Health and Human Services U.S. License No. 1888. Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test is indicated for 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 five substances included on the Rubber Panel T.R.U.E. TEST.

The review of this product was associated with the following National Clinical Trial (NCT) number: 00795951

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test at your facility located in Hillerod, Denmark. You may label your product with the proprietary name Rubber Panel T.R.U.E. TEST and market it in a multipack carton containing five units. Each unit consists of one adhesive panel containing six patches.

Each panel contains one negative control and five rubber allergens: Carba Mix, 0.25 mg/cm^2; Black Rubber Mix, 0.075 mg/cm^2; Mercaptobenzothiazol, 0.075 mg/cm^2; Mercapto Mix, 0.075 mg/cm^2; and Thiuram Mix, 0.027 mg/cm^2.

ADVISORY COMMITTEE

We did not refer your application to the Allergenics Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test shall be 24 months from the date of manufacture when stored at room temperature 20 – 25 °C (68 – 77 °F). The date of manufacture shall be defined as the date of initiation of final product assembly.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, 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

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of Rubber Panel Thin-Layer Rapid Use Epicutaneous Patch Test, or in the manufacturing facilities.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 25, dated November 16, 2016 and the draft carton and container labeling submitted under amendment 21, dated May 2, 2016.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to this BLA 125579 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)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80) and you must submit distribution reports as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format —Postmarketing Safety Reports* at

http://www.fda.gov/Drugs/DrugSafety/ucm400526.htm and FDA's Adverse Event reporting System website http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm.

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 are waiving the pediatric study requirement for ages birth to six years because necessary studies are impossible or highly impracticable. This is because contact dermatitis due to rubber allergens included in your product is uncommon in patients less than 6 years of age.

This product is appropriately labeled for use in ages 6 to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

We note that you have fulfilled the pediatric study requirement for ages 6 to 17 years for this application.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely yours,

Marion F. Gruber, Ph.D.
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research