**CONSENT FOR SKIN PRICK TESTING USING PRODUCTS THAT**

**ARE NOT CURRENTLY TGA REGISTERED IN AUSTRALIA**

Skin prick testing is the primary mode of testing for immediate IgE-mediated allergy. This testing is widely practiced, carries very low risk of side effects to patients and provides high quality information when performed optimally and interpreted correctly.

Food allergen extracts for skin prick testing that were registered with the Therapeutic Goods Administration (TGA) for use in Australia were discontinued in 2008 and are therefore no longer available. Since 2008 it has been necessary for specialist physicians to use other products that are not currently TGA registered.

The benefits and risks of using products supplied by Stallergenes (Alyostal) or Australasian Medical and Scientific (ALK-Abello and Diater-DAP) that are not currently TGA registered are no different to the TGA registered products.

Specialist physicians who are skilled in allergy testing can access the unregistered products by obtaining Section 19(5) of the Therapeutic Goods Act 1989 Authorised Prescriber status from the TGA by endorsement from a medical College or ethics committee.

Patient consent needs to be obtained before the use of products that are not TGA registered.

Once completed and signed this form is kept on file by your treating specialist physician.

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Name of patient or parent/guardian)

understand that the product being used is not currently TGA approved for use in Australia and

has been approved under the provisions of Section 19(5) of the Therapeutic Goods Act 1989.

The Commonwealth cannot therefore guarantee the quality, safety or efficacy of the product.

Patient’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Treating physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_