



Memorandum

Date February 10, 2017

From Colleen Sweeney, R.N., M.S.
BLA Committee Chair
Division of Vaccines and Related Products Applications (DVRPA)

Subject BLA: STN 125592/0 Proper name suffix addition for House Dust Mite Allergen Extract

To The File

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. (the Applicant) submitted a Biologics License Application (BLA), STN 125592 on February 9, 2016, for licensure of House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract. The proprietary name is ODACTRA™ and the dosage form for this product is a tablet for sublingual use. ODACTRA is an allergen extract indicated as immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by *in vitro* testing for IgE antibodies to *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* house dust mites, or skin testing to licensed house dust mite allergen extracts. ODACTRA is proposed for use in adults 18 through 65 years of age.

This memo is to address that the FDA issued a final guidance entitled, “*Nonproprietary Naming of Biological Products*,” on January 13, 2017 stating the Agency’s intention to designate proper names for certain biological products that include four-digit distinguishing suffixes. However, we are unable to designate a suffix for House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract as there is insufficient time to allow for the necessary logistics and review between the guidance issuing and the product’s approval. The addition of a suffix can be addressed retrospectively as described in the guidance.