

**From:** Sweeney, Colleen  
**Sent:** Thursday, March 31, 2016 8:19 PM  
**To:** Margaretten, Nadine ([nadine\\_margaretten@merck.com](mailto:nadine_margaretten@merck.com))  
**Subject:** RE: Proprietary Name Acceptance and Proper Name

Dear Dr. Margaretten:

We have reviewed your submission dated February 19, 2016, to your biologics license application (BLA) for House Dust Mite (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*) Allergen Extract requesting a proprietary name review (PNR).

In consultation with CBER's Advertising and Promotional Labeling Branch (APLB) we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, ODACTRA, is acceptable.

If you have any questions, please contact CAPT Colleen Sweeney or LCDR Matthew Steele at 301-796-2640

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