

MEMORANDUM

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research**

Date: March 10, 2016

From: CDR Oluchi Elekwachi, PharmD, MPH
Regulatory Review Officer
Advertising and Promotional Labeling Branch (APLB)
Division of Case Management (DCM)

Through: Lisa L. Stockbridge, Ph.D.
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To: Colleen Sweeney, RPM, OMPT/CBER/OVRR/DVRPA/CMC1
Kathleen Hise, Medical Officer, OMPT/CBER/OVRR/DVRPA/CRB1

Subject: Review of Proposed Proprietary Name **ODACTRA** (House Dust Mites Allergen Extract)
BLA 125592/0/1
MERCK SHARP and DOME

Recommendation: ODACTRA - Acceptable

Executive Summary

APLB has completed the review of the proposed proprietary name (PNR), **ODACTRA**, and recommends that **ODACTRA** be found **Acceptable**.

Pursuant to SOPP 8001.4 (Review of CBER Regulated Product Proprietary Names), the product office, Office of Vaccine Research and Review (OVRR), makes the final decision on the acceptability of proposed proprietary names. To meet the PDUFA performance goal, the product office must communicate this decision to the sponsor, Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., within 90 days of the receipt of the complete PNR submission. The PDUFA goal date for this PNR is May 16, 2016.

If OVRB accepts our recommendation that the proposed proprietary name, **ODACTRA**, be found acceptable, we offer the following communication-ready language:

*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.*

OVRB is responsible for communicating CBER's decision to Merck Sharp & Dohme Corp., and should enter the communication issuance date into RMS-BLA before May 16, 2016, in order to meet the deadline and stop the performance clock. Please notify APLB when this action is completed.

Background

On February 16, 2016, Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., (Merck) submitted a proposed proprietary name review request for **ODACTRA**, their sublingual allergenic extract of house dust mite (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*).

According to the sponsor, the name **ODACTRA** (pronounced *OH-dak-trah*), has no intrinsic meaning. It will be indicated as immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for *Dermatophagoides farinae* or *Dermatophagoides pteronyssinus* IgE antibodies.

The product is circular freeze-dried sublingual tablets. The sponsor has requested a novel unit of measure, the "SQ-HDM," to express the strength. **ODACTRA** will be supplied in 3 blister packages of 10 tablets (30 tablets total), which should be stored at controlled room temperature, 20°C-25°C (68°F-77°F). It must be stored in the original package until use to protect from moisture. The first dose of **ODACTRA** will be given by a physician with experience in the diagnosis and treatment of allergic diseases; subsequent doses will be self-administered at home. A starter pack will be made available from the prescriber, with further dispensing from a retail pharmacy setting.

Method

APLB utilized the FDA Phonetic and Orthographic Computer Analysis (POCA) with the following databases:

1. Google Internet search at <https://www.google.com/>
2. CBER list of Licensed Products through March 8, 2016, at <http://www.fda.gov/BiologicsBloodVaccines/ucm133672.htm>
3. Micromedex at <http://www.micromedexsolutions.com/micromedex2/librarian>
4. Drugs@FDA current through March 8, 2016, at

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>

5. DailyMed at <http://dailymed.nlm.nih.gov/dailymed/about.cfm>
6. United States Patent and Trademark Office at <http://www.uspto.gov/>
7. United States Adopted Names at <http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council.page>
8. Drug Facts and Comparisons at <http://online.factsandcomparisons.com/index.aspx?>
9. Merriam-Webster Dictionary at <http://www.merriam-webster.com/>

Discussion

1. Prescreening for Objectionable Naming Practices

The proposed name, **ODACTRA**, was screened against the following:

- Obvious similarities in spelling and pronunciation
- Manufacturing characteristics
- Medical and/or coined abbreviations
- Inert or inactive ingredients
- Combination of active ingredients
- United States Adopted Name (USAN) stems
- Same proprietary name for products containing different active ingredients
- Reuse of proprietary names
- Dosage form or route of administration
- Dosing interval
- Established or proper name
- Modifiers as components of a proprietary name
 - Use of numerals as modifiers
 - Device-related modifiers
 - Descriptive modifiers
- Brand name extensions (Umbrella branding)
- Dual proprietary names
- Foreign drug proprietary name
- Prescription-to-OTC switch
- Use of symbols
- Incorporation of the sponsor's name

2. Evaluating for Promotional and Safety Concerns

a. Promotional Review [21 CFR 201.10 (c)(3), 202.1 (e)(5)(i), and (e)(6)(i)]

The proposed proprietary name, **ODACTRA**, is not regarded to be false or misleading.

b. Look-alike Sound-alike Safety Review [21 CFR 201.10 (c)(5)]

Since drug products are prescribed through written, verbal, and/or electronic orders, such forms of communication may lead to medication errors, particularly if proprietary or proper names sound or look alike. APLB conducted searches using POCA, with Drugs@FDA, RxNorm, Orange Book, and names entered by evaluators as data sources, to identify names with potential similarity to the proposed name, **ODACTRA**. Any name with an orthographic and phonetic combined match percentage score greater than 70% is considered to be “highly similar,” and names between 50% and 69% are considered to be “moderately similar.”

Differences in dose, strength, and dosage form may decrease the risk of medication error among moderately similar names. The search yielded 117 names, all of which were moderately similar. With the exception of **ORACEA**, all 117 names had very different dose, strength, and dosage form from **ODACTRA**. **ORACEA** is a 40 mg oral capsule for the skin lesions in adult rosacea patients. Its dose, strength, and dosage form differences reduces its risk of confusion with **ODACTRA**. For consideration, APLB notes that **ORACEA** has a similar administration (oral vs. sublingual) and likely will be dispensed in the same environment as **ODACTRA**.

Recommendation

APLB recommends that the proposed proprietary name, **ODACTRA**, be found **Acceptable**.

If you have any questions with regard to this review please contact CDR Oluchi Elekwachi, Regulatory Review Officer, at 240-402-8930.