Our STN: BL 125592/218

SUPPLEMENT APPROVAL
PMR/PMC FULFILLED

ALK-Abello A/S
Attention: William Gray
ALK-Abello Inc.
135 Route 202/206 Suite 16
Bedminster, NJ 07921

February 27, 2025

Dear Mr. Gray:

We have approved your request received April 29, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract (ODACTRA), manufactured at your Horsholm, Denmark location, to include use in children 5 through 11 years of age.

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT03654976 and NCT04145219.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling: Package Insert submitted under amendment 14, dated February 24, 2025; Medication Guide submitted under amendment 11, dated January 10, 2025; and the draft carton and container labels submitted April 29, 2024.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted February 24, 2025, and Medication Guide submitted on January 10, 2025. 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.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on April 29, 2024, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125592 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the change approved today.

FULFILLED POSTMARKETING REQUIREMENT

This submission fulfills your postmarketing requirement PMR #1 identified in the January 20, 2023, letter issued for STN BL 125592/157 for House Dust Mite (*Dermatophagoides farinae* and *Dermatophagoides pteronyssinus*) Allergen Extract (ODACTRA). The requirement addressed in this submission is as follows:

1. Deferred pediatric study (Study MT-12) under PREA to evaluate the safety, tolerability, and efficacy of ODACTRA in pediatric subjects 5 through 11 years of age with house dust mite-induced allergic rhinitis/rhinoconjunctivitis with or without asthma.

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 note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Jay Slater, MD
Director
Division of Bacterial, Parasitic and Allergenic Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research