Our STN: BL 125478/293

SUPPLEMENT APPROVAL
PMR FULFILLED

April 16, 2021

ALK-Abello A/S
Attention: Mr. William Gray
Director, Regulatory Affairs Americas
135 Route 202/206 Suite 3
Bedminster, NJ 20879

Dear Mr. Gray:

We have approved your request submitted and received June 17, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Short Ragweed Pollen Allergen Extract manufactured at your (b) (4) location for use in children and adolescents 5 to 17 years of age. Short Ragweed Pollen Allergen Extract is indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen. RAGWITEK is approved for use in persons 5 through 65 years of age.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT02478398.

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 package insert labeling submitted and received on April 15, 2021 under amendment #16, the Medication Guide submitted and received on April 09, 2021 under amendment #13, and the draft trade and sample carton and container labels submitted and received on April 08, 2021 under amendment #12.

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 on April 15, 2021 and Medication Guide submitted on April 09, 2021. 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 08 2021, 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 125478 at the time of use (prior to marketing) 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)).

FULFILLED POSTMARKETING REQUIREMENT

This submission fulfills your postmarketing requirement (PMR) #1 identified in the April 17, 2014, Approval Letter for BLA STN 125478/0 for Short Ragweed Pollen Allergen Extract (RAGWITEK). The requirement addressed in this submission is as follows:

1. Deferred pediatric study protocol #P008, under PREA to evaluate both safety and efficacy of RAGWITEK as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen in pediatric subjects 5 to 17 years of age.

   Final Protocol Submission: December 31, 2014

   Study Completion Date: December 31, 2018

   Final Report Submission: September 30, 2019

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,

Doran Fink, M.D., Ph.D.
Deputy Director-Clinical
Division of Vaccines
and Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research