



SUPPLEMENT APPROVAL

Our STN: BL 125473/353

ALK - Abello A/S
Attention: William B. Gray
135 Route 202/206 Suite 3
Bedminster, NJ 07921

January 8, 2020

Dear Mr. Gray:

We have approved your request submitted, and received, June 27, 2019, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Timothy Grass Pollen Allergen Extract (GRASTEK), manufactured at your Horsholm, Denmark facility to update the United States Package Insert labeling to comply with 21 CFR 201.57(c)(9)(i) - (iii) to address the Pregnancy, Lactation and Labeling Rule.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 1, dated January 3, 2020, and the draft Medication Guide submitted on June 27, 2019.

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>. 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.

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)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these change(s).

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

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