



**ASSIGN / APPROVE**

OUR STN: BL 125473/276

Merck Sharp & Dohme Corp.  
Attention: Shawn Moylan  
1 Merck Drive  
P.O. Box 100  
Whitehouse Station, NJ 08889-0100

April 28, 2017

Dear Mr. Moylan:

Submission Tracking Number (STN) BL 125473/276 has been assigned to your recent supplement to your biologics license application for Timothy Grass Pollen Allergen Extract (GRASTEK) dated December 9, 2016. Your submission is in the form of a "Prior Approval Supplement" (21 CFR 601.12(b)) that requires CBER approval prior to the distribution of product made using the changes.

We have approved your request dated December 9, 2016, to supplement your Biologics License Application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Timothy grass pollen allergen extract (GRASTEK) to include changes to the package insert to add "stridor" as a post-marketing adverse reaction.

We hereby approve the draft package insert labeling submitted on April 13, 2017 and the US Medication Guide submitted on April 13, 2017.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to BLA 125473 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in 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>.

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 this change.

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

Wellington Sun, MD  
Director  
Division of Vaccines and  
Related Products Applications  
Office of Vaccine  
Research and Review  
Center for Biologics  
Evaluation and Research