SUPPLEMENT APPROVAL

OUR STN: BL 101844/5193

Greer Laboratories, Inc
Attention: Mark Hites
639 Nuway Circle, NE
P.O. Box 800
Lenoir, NC 28645-0800

August 23, 2017

Dear Mr. Hites:

At this time we are issuing this letter of correction to the July 27, 2017, approval letter. This language supersedes the language in the approval letter of July 27, 2017.

We have approved your request dated January 26, 2017, to supplement your Biologics License Application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Short Ragweed Pollen Allergenic Extract and Short and Giant Ragweed Pollen Mix Allergenic Extract to convert the package insert to comply with the Physician's Labeling Rule.

We hereby approve the draft package insert and container labeling submitted to us on July 27, 2017.

We acknowledge your final draft labeling and container label submitted on August 10, 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 101844 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 these change(s).

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 Product Applications
Office of Vaccine
Research and Review
Center for Biologics
Evaluation and Research