SUPPLEMENT APPROVAL

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

January 5, 2018

Dear Mr. Hites:

We have approved your request dated July 7, 2017, to supplement your Biologics License Applications (BLA) to include conversion of the package insert to comply with the Physician's Labeling Rule for the following products:

STN	Name of Biological Products
BL 101836/5069	Bermuda Grass Pollen *(Cynodon dactylon)*
BL 101837/5069	Kentucky (June) Bluegrass Grass *(Poa pratensis)*
BL 101838/5071	Meadow Fescue Grass *(Festuca elatior)*
BL 101839/5064	Orchard Grass *(Dactylis glomerata)*
BL 101840/5070	Redtop Grass *(Agrostis alba)*
BL 101841/5066	Perennial Rye Grass *(Lolium perenne)*
BL 101842/5066	Sweet Vernal Grass *(Anthoxanthum odoratum)*
BL 101843/5070	Timothy Grass *(Phleum pratense)*

We hereby approve the draft package insert labeling submitted to us as an amendment dated January 4, 2018, and the draft carton and container labeling submitted in an amendment dated December 11, 2017.

Please provide your final content of labeling including the carton and container labels in Structured Product Labeling (SPL) format. All final labeling should be submitted as Product Correspondence to BLA STN 101836 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)).

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