Our STN: BL 101833/5130 **SUPPLEMENT APPROVAL**

Greer Laboratories, Inc
Attention: Mark Hites
639 Nuway Circle
Lenoir, NC 28645-0800

April 9, 2019

Dear Mr. Hites:

We have approved your request submitted on July 20, 2018, received on July 23, 2018, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Multiple Products: Non-standardized Allergenics, manufactured at your Lenoir, NC, location to include conversion of the package insert to comply with the Physician's Labeling Rule and the addition of 2D bar codes and serialization to the carton and container labels to comply with the Drug Safety and Supply Chain Act.

Under this approval, your request for a waiver from the requirement to include a full listing of all product dosage forms and associated NDCs in Section 16.1 of the package insert is granted. As an alternate approach, you will include a list of all available allergens in Section 16.1 of the package insert. In addition, you will submit complete information on all products manufactured at your North Carolina facility in accordance with the drug listing requirements under 21 CFR 207.49.

LABELING

We hereby approve the draft package insert labeling submitted under amendment, dated March 22, 2019, and the draft carton and container labeling submitted July 23, 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.

PACKAGE AND CONTAINER LABELS

Please electronically submit final printed package and container labels that are identical to the package submitted March 22, 2019 and container labels submitted on July 23, 2019, 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/downloads/drugs/guidancecompliance regulatoryinformation/guidances/ucm333969.pdf.

All final labeling should be submitted as Product Correspondence to BLA 101833 at the time of use (prior to marketing) and should 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)).

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