SUPPLEMENT APPROVAL
March 6, 2026

Jubilant HollisterStier LLC
Attention: Mr. Curtis Efta
3525 N. Regal Street
Spokane, WA 99207

Dear Mr. Efta

We have approved your requests received July 25, 2025, to supplement your Biologics License Applications (BLAs) submitted under section 351(a) of the Public Health Service Act to convert the package insert to the Physician Labeling Rule (PLR) format for the following products:

STN	Name of Biological Product
BL 103872/5257	Standardized Bermuda Grass (*Cynodon dactylon*) Grass Pollen
BL 103837/5261	Standardized Bluegrass, Kentucky (June) (*Poa pratensis*) Grass Pollen
BL 103874/5246	Standardized Meadow Fescue (*Festuca elatior*) Grass Pollen
BL 103875/5244	Standardized Orchard (*Dactylis glomerata*) Grass Pollen
BL 103876/5245	Standardized Redtop (*Agrostis alba*) Grass Pollen
BL 103877/5244	Standardized Perennial Rye (*Lolium perenne*) Grass Pollen
BL 103878/5244	Standardized Sweet Vernal (*Anthoxanthum odoratum*) Grass Pollen
BL 103879/5246	Standardized Timothy (*Phleum pratense*) Grass Pollen

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 3, dated March 5, 2026.

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 https://www.fda.gov/industry/fda-data-standards-advisory-board/structured-product-labeling-resources. Content of labeling must be identical to the Package Insert submitted on March 5, 2026. 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 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/spl-standard-content-labeling-technical-qs.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 103872/5257 at the time of use and 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

We will include information contained in the above-referenced supplements in your BLA files.

Sincerely,

Andrea Hulse, MD, for
Acting Division Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research