Our STN: BL 103257/5090 **SUPPLEMENT APPROVAL**

Nielsen Bioscience, Inc.
Attention: David P. Burney
11125 Flintkote Avenue
Suite G
San Diego, CA 92121

September 20, 2021

Dear Mr. Burney:

We have approved your request submitted January 11, 2021, received January 12, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Candida albicans Skin Test Antigen, for Cellular Hypersensitivity (CANDIN) manufactured at your Convoy Court, San Diego, CA, facility, to include a change in the potency release test from human to guinea pig and to include the addition of a manufacturing location for housing and testing of animals used in potency testing of the final drug product.

Under this approval, the additional manufacturing location is at (b) (4) . You will use this location to house guinea pigs for drug product potency testing and will perform the potency test at this location.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted August 30, 2021, and received August 31, 2021.

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. Content of labeling must be identical to the Package Insert, submitted on February 10, 2021. 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.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 103257 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)).

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 changes.

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

Sincerely,

Jay E. Slater, M.D.
Director
Division of Bacterial, Parasitic
and Allergenic Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research