



NDA 204677/S-023

## SUPPLEMENT APPROVAL

Life Molecular Imaging Ltd.  
c/o CBR International  
Attention: Jeanne Novak, Ph.D.  
Head of DDC  
2905 Wilderness Place  
Suite 202  
Boulder, CO 80301

Dear Dr. Novak:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 5, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Neuraceq (florbetaben F 18 injection).

This “Changes Being Effected” supplemental new drug application provides for the addition of the drug product vial and shield labels for the newly approved manufacturer, Jubilant Radiopharma, Yardley, PA.

### **APPROVAL & LABELING**

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on May 5, 2023, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 204677/S-023.**” Approval of this submission by FDA is not required before the labeling is used.

If you have any questions, call Anika Lalmansingh, Ph.D., Senior Regulatory Business Process Manager, at (240) 402 - 0356.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, Ph.D.  
Chief, Branch I  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures:

Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
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