NDA 202008/S-041

APPROVAL LETTER

Avid Radiopharmaceuticals Inc.
Attention: Stephen Truocchio
Associate VP - Global Regulatory Affairs - North America
3711 Market Street, 7th Floor
Philadelphia, PA 19104

Dear Mr. Truocchio:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 3, 2022, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Amyvid (Florbetapir F 18 Injection).

This Prior Approval supplemental new drug application provides for:

- Addition of a manufacturing process for (b) (4) AV-105 close to or beyond the current expiry period.
- Addition of (b) (4) as a new container closure for the storage of (b) (4) AV-105.
- Addition of (b) (4) as a manufacturer of (b) (4) AV-105 and Release Testing, Warehousing and Dispensing operations.
- Addition of (b) (4) as a manufacturer for AV-105 Reference Standard.
- Addition of (b) (4) for Release Testing of AV-105.

APPROVAL

We have completed our review of this supplemental application, as amended. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, PhD
Branch Chief, B1
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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