



NDA 208700/S-020

SUPPLEMENT APPROVAL

Advanced Accelerator Applications USA, Inc.
Attention: Jouliana Jean Paul, J.D.
Global Program Regulatory Director
57 E. Willow Street
Millburn, NJ 07041

Dear Ms. Paul:

Please refer to your supplemental new drug application (sNDA) dated and received December 17, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LUTATHERA (lutetium Lu 177 dotatate) injection.

This Prior Approval sNDA provides for updates to the carton and container labeling, including the addition of a 2D matrix code for product traceability, increase in vial/lead shielding label sizes, and editorial changes.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELING

We acknowledge your December 17, 2021, submission containing final printed carton and container labeling.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Emily Pak, Regulatory Health Project Manager, at 301-837-7531.

Sincerely,

{See appended electronic signature page}

Martha Donoghue, M.D.
Deputy Director
Division of Oncology 2
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARTHA B DONOGHUE
06/06/2022 07:28:31 AM