U.S. FOOD & DRUG ADMINISTRATION

Barinder Kang
VP & Head of Radioligand Therapy Team (RLT)
Advanced Accelerator Applications USA, Inc., A Novartis Company
One Health Plaza
East Hanover, NJ 07936

October 7, 2024

Re: Docket No. FDA-2024-P-1871

Dear Dr. Kang:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 15, 2024. Your petition requests that the Agency

> ensure that applications submitted under 505(j) and 505(b)(2) that rely on Lutathera include data necessary to show that a proposed product is pharmaceutically equivalent, bioequivalent, and can be expected to have the same clinical effect and safety profile as Lutathera when administered to patients under the conditions specified in the labeling, including Total Activity at time of injection, Specific Activity at time of calibration, and individual patient doses filled in the range 20.5-25.0 mL to ensure Total Activity of 7.4 GBq at time of injection.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2024.10.07 09:40:51 -04'00'

Carol J. Bennett
Acting Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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