



October 31, 2022

Kurt R. Karst
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Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug refuse to approve any NDA seeking approval of a conventional Tc-99m generator or Tc-99m product that relies on neutron capture technology given the advances in Tc-99m production that renders such an approach obsolete was received and processed under CFR 10.30 by this office on 10/28/2022.

It was assigned docket number FDA-2022-P-2702. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)

cc: aevans@hpm.com