Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005-5929

November 21, 2022

Re: Docket No. FDA-2022-P-2702

Dear Mr. Karst:

This letter responds to your petition dated October 28, 2022 (Petition). The Petition requests that the U.S. Food and Drug and Administration (FDA or the Agency) "refuse to approve any NDA [New Drug Application] 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" (Petition at 2).

For the reasons described below, FDA denies the Petition without substantive evaluation.

I. DISCUSSION

Under FDA's regulations at 21 CFR 10.31, any petition that requests that the Commissioner take any form of action that could, if taken, delay approval of an NDA submitted under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act must include the following certification:

> I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____[in the blank space, provide the date on which such information first became known to the person submitting the petition]. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ [in the blank space, provide the names of such persons or organizations]. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

Your Petition explicitly requests that FDA refrain from approving an NDA "*including any 505(b)(2) NDA* seeking approval of [Tc-99m] produced in conventional generators . . . by way of neutron capture technology" (emphasis added) (Petition at 1). In doing so, the Petition necessarily seeks to prevent or delay approval of any 505(b)(2) NDA for Tc-99m, and accordingly, falls within the scope of 21 CFR 10.31. FDA will not consider your Petition for review unless it contains the certification described in 21 CFR 10.31(c).

We thus deny your Petition under 21 CFR 10.31(c), without evaluating the claims and information contained in the Petition. If you would like FDA to consider such information and to

evaluate your claims, please submit a new citizen petition under 21 CFR 10.30 and include the certification described in 21 CFR 10.31(c).

II. CONCLUSION

For the reasons described, the Agency denies the Petition.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2022.11.18 13:20:41 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research