March 14, 2022

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

Sent via email to: KKarst@hpm.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug assign in the Agency's Orange Book a TE Code of "AP" to the 60 mg/0.2 mL, 90 mg/0.3 mL, and 120 mg/0.5 mL, drug products approved under NDA 215395 for InvaGen's Lanreotide Injection was received and processed under CFR 10.30 by this office on 03/11/2022.

It was assigned docket number FDA-2022-P-0329. 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,

Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2022.03.14 11:06:45 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)