April 9, 2020

Andrew J. Sansone, MS
Vice President, Regulatory Affairs, Quality & Safety
Ipsen Biopharmaceuticals, Inc.
One Main Street, Unit 700
Cambridge, MA 02142

Re: Docket No. FDA-2019-P-4830

Dear Mr. Sansone:

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 October 15, 2019. Your petition requests that the Agency require any abbreviated new drug application for a proposed generic version of Somatuline Depot (lanreotide acetate) to conduct *in vivo* studies to demonstrate bioequivalence.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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 we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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Date: 2020.04.07 09:07:55 -04'00'

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

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