DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

October 16, 2019

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

Sent via email: andrew.sansone@ipsen.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA determines that any proposed generic version of Somatuline Depot must be tested in vivo to assure that it is bioequivalent to Somatuline Depot was received by this office on 10/15/2019.

It was assigned docket number FDA-2019-P-4830. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby

Digitally signed by Dynna Bigby
Date: 2019.10.16 16:43:46 -04'00'

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