DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

March 3, 2020

Edgar Sanchez Palacios
CellTrion, Inc.
One Evertrust Plaza, Suite 1207
Jersey City, NJ 07302

Sent via email to: US-Agent@celltrion.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to designate a suitable alternative RS from the listed drugs in the Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book) for Ropinirole Hydrochloride Extended- Release Tablets, for purpose of conducting bioequivalence studies to support a post-approval Supplement for ANDA 091395 (Ropinirole Hydrochloride Extended Release Tablets, 2 mg, 4 mg, 6 mg, 8 mg and 12 mg) was received by this office on 03/02/2020.

It has been assigned docket number FDA-2020-P-1016. 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: 2020.03.03 16:06:04 -05'00'

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