U.S. FOOD & DRUG ADMINISTRATION

Edgar Sanchez Palacios
US Agent for Celltrion, Inc.
One Evertrust Plaza, Suite 1207
Jersey City, NJ 07302

August 26, 2020

Re: Docket No. FDA-2020-P-1016

Dear Mr. Palacios:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted by Celltrion on March 3, 2020. Your petition requests that the Agency designate ropinirole hydrochloride extended release tablets, 2 milligrams, abbreviated new drug application 201576 held by Dr. Reddy's Laboratories Ltd, as a reference standard.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Elizabeth R. Jungman -S

Digitally signed by Elizabeth R. Jungman -S
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Date: 2020.08.25 17:59:24 -04'00'

Carol J. Bennett
Deputy Director
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