DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

October 25, 2019

Madan Chilakuri M.S.; R.Ph.
VP of Quality & Regulatory Affairs
Andersen Pharma LLC
20925 W Field Pkwy, Suite 205
Deer Park IL 60010

Sent via email: mchilakuri@andersen-pharma.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting Requests that the FDA declare the drug product, Magnesium Sulfate in Dextrose 5% Injection, USP, in the total drug content strength of 1 gm/50 mL is suitable for submission in an ANDA. The Reference Listed Drug ("RLD") upon which this petition is based is Hospira Inc NDA 020309 for Magenisum Sulfate in Dextrose 5% in plastic Container, in a 2 gm/100 mL strength. Your petition was received by this office on 10/25/2019.

It was assigned docket number FDA-2019-P-4979. 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,

Karen Kennard -S
Digitally signed by Karen Kennard -S
Date: 2019.10.28 10:10:06 -04'00'

Karen Kennard
Director
Dockets Management Staff
FDA/Office of Operations (OO)