



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 05, 2020

Ariadna Olle
Medichem, S.A.
Fructuos Gelabert, 6-8, ant Joan Despi,
Barcelona, SPAIN 08970

Sent via email to: aolle@medichem.es

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to take action declaring that the drug product, Rufinamide 800 mg film-coated tablets, is suitable for submission as an ANDA was received by this office on 02/04/2020.

It was assigned docket number FDA-2020-P-0624. 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
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)