



May 6, 2022

Frederik Defesche
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Sent via email to: fdefesche@regconsolutions.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug to make a determination that Lacosamide Injection USP 100mg/10mL (10mg/mL) is suitable for submission as an ANDA was received and processed under CFR 10.30 by this office on 05/05/2022.

It was assigned docket number FDA-2022-P-0747. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

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