Newcastle
BIOSCIENCE

July 31st, 2024

VIA ELECTRONIC SUBMISSION 7/31/24

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

AMENDMENT TO FDA-2024-P-3293

Dear Sir or Madam:

Newcastle received an email from Project Manager Kim-Yen Nguyen. In that email it was pointed out that there was an error in the strengths of Lacosamide ODT being requested for consideration as suitable for an ANDA filing. Reference was made in the original suiability petition letter dated July 9th, 2024 and assigned docket # 2024-P-3293 to a 125 mg strength in four areas of the original letter.

The purpose of this letter is to clarify that a 112.5 mg strength is being requested not the 125 mg strength. The 112.5 mg strength corresponds with the proposed labeling. We apologize for this administrative error and have attached a revised Suitability Peition Letter with the correction as Attachment 1 to this letter in case this is required by the Agency.

Respectfully submitted,

Gene Nakagawa
President
Newcastle Bioscience LLC
gene@newcastlebio.com
Mobile: 310-936-0931

Attachments: 1. Petition Letter Updated