Newcastle Bioscience, LLC
999 Vanderbilt Beach Road
Suite 200
Naples, FL 34108
Attn: Gene Nakagawa

Sent via email to: gene@newcastlebio.com

Docket No. FDA-2024-P-1870

Dear Gene Nakagawa:

This is in response to your petition received on April 15, 2024, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Escitalopram Oxalate Orally Disintegrating Tablets (ODT), 5 mg, 10 mg, 15 mg and 20 mg. The listed drug product to which you refer in your petition is Lexapro (Escitalopram Oxalate) Tablets, 5 mg, 10 mg, and 20 mg, approved under NDA 021323 and held by Abbvie, Inc.

Your request involves a change in strength and dosage form from that of the listed drug product (i.e., from Escitalopram Oxalate Tablets, 5 mg, 10 mg, and 20 mg to Escitalopram Oxalate Orally Disintegrating Tablets, 5 mg, 10 mg, 15 mg, and 20 mg). The change that you request is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act.

We have reviewed your petition under section 505(j)(2)(C) of the Act and FDA's implementing regulations at 21 CFR 314.93 and have determined that it is approved. This letter represents FDA's determination that an ANDA may be submitted for the above-referenced drug product.

Under section 505(j)(2)(C) of the Act and 21 CFR 314.93(e)(1), FDA will approve a petition properly submitted under § 314.93 seeking a strength and dosage form that differs from the strength and dosage form of the listed drug product unless it finds that one of the grounds for denying such a petition applies.

The Agency finds that the proposed change in strength and dosage form for the proposed drug product does not pose questions of safety or effectiveness. The uses and route of administration of the proposed drug products are the same as those of the listed drug product. The proposed changes are also consistent with dosing recommendations in the labeling of the listed drug. In addition, if shown to meet bioequivalence requirements, the proposed drug products can be expected to have the same therapeutic effect as the reference listed drug

products. Therefore, FDA concludes that the proposed changes would not jeopardize the safe or effective use of the product so as to necessitate significant labeling changes, and investigations are not necessary to show the safety and effectiveness of the proposed strength and dosage form.

In addition, this petition and your waiver request were evaluated with respect to the Pediatric Research Equity Act (PREA). PREA provides that a person who submits an application or supplement under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall submit assessments adequate to evaluate the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration in each pediatric subpopulation for which the drug is safe and effective, unless this requirement is waived. Section 505B of the Act. If a change proposed in a suitability petition triggers the need for pediatric studies under PREA to assess safety and efficacy in a relevant pediatric subpopulation and FDA does not waive the requirement, the proposed product will not be eligible to be approved in an ANDA and the suitability petition must be denied. *See* section 505(j)(2)(A) of the Act ("The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii) [of Section 505(j)(2)(A)].").

The Agency has determined that your proposed change in dosage form is subject to PREA, but has concluded that investigations are not necessary to demonstrate the safety and effectiveness of your proposed product in pediatric patients under 7 years of age with MDD or GAD, because studies are impossible or highly impracticable in these patient populations. Furthermore, the drug product is appropriately labeled for use in pediatric patients ages 7 years of age and older with MDD or GAD.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that FDA has determined that an ANDA will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by FDA.

To permit review of your ANDA submission, you must submit all information required under section 505(j)(2)(A) and (B) of the Act. To be approved, the drug product will, among other things, be required to meet current bioequivalence requirements under section 505(j)(2)(A)(iv) of the Act. During the review of your application, FDA may require the submission of additional information.

The listed drug products to which you refer in your ANDA must be the ones upon which you based this petition. In addition, you must refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission. 21 CFR 314.94(a)(3)(iii). Please note that once a new drug application is approved for a product that is the same as the subject of an

approved petition such petition may not be utilized as the basis for submission of an ANDA.

A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

William Chong, M.D.
Director
Office of Safety and Clinical Evaluation
for Iilun Murphy, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

William Chong

Digitally signed by William Chong
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