NDA 021519/S-021

SUPPLEMENT APPROVAL

ANI Pharmaceuticals, Inc.
Attention: Justin E. Uthup
Director, Regulatory Affairs
210 Main Street West
Baudette, MN 56623

Dear Mr. Uthup:

Please refer to your supplemental new drug application (sNDA) dated and received June 1, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Luvox (fluvoxamine maleate) Tablets USP, 25 mg, 50 mg, and 100 mg.

We also refer to our approval letter dated September 20, 2022, which contained the following error: 9 month time point was omitted from the "Provides for" statement.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain September 20, 2022, the date of the original approval letter.

This Prior Approval supplemental new drug application provides for revising the routine stability protocols for all three strengths to an annual testing schedule for the Annual Commitment batches only, by removing 3 month, 6 month, **9 month**, and 18 month time points and implement an annual testing schedule for the Annual Commitment batches associated with Fluvoxamine Maleate Tablets USP, 25 mg, 50 mg, and 100 mg.

APPROVAL

We have completed our review of this supplemental application. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kimberly Hudgens, Regulatory Business Process Manager, at (240) 402 - 4884.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, B3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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