



NDA 019906/S-041

**SUPPLEMENT APPROVAL**

SpecGx LLC  
Attention: Donatus Ako-Arrey  
Sr. Director of Regulatory Affairs  
385 Marshall Avenue  
Webster Groves, MO 63119

Dear Mr. Ako-Arrey:

Please refer to your Supplemental New Drug Application (sNDA) dated August 3, 2018, received August 3, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Anafranil (clomipramine hydrochloride) Capsules, 25 mg, 50 mg, and 75 mg.

This “Changes Being Effected” supplemental new drug application proposes carton and container labeling changes to revise the established name presentation to ClomiPRAMINE Hydrochloride as requested in an Agency letter dated July 6, 2018.

**APPROVAL & LABELING**

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**CARTON AND IMMEDIATE CONTAINER LABELS**

We acknowledge your August 3, 2018, submission containing final printed carton and container labels.

**REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have questions, contact Danbi Lee, Regulatory Project Manager at [danbi.lee@fda.hhs.gov](mailto:danbi.lee@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Mitchell V. Mathis, MD  
Director  
Division of Psychiatry Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

ENCLOSURE:  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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MITCHELL V Mathis  
08/22/2018

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