October 21, 2024

John Sharretts, M.D, Director
Center for Drug Evaluation and Research
Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Office of Cardiology, Hematology, Endocrinology
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Food and Drug Administration
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

REQUIRED PEDIATRIC STUDIES UNDER PEDIATRIC RESEARCH EQUITY ACT (PREA)

Re: NDA 200063 Serial Number 0224
Naltrexone HCl and Bupropion HCl Extended-Release Tablets
RESPONSE TO PREA NONCOMPLIANCE LETTER: PMR 2778-3, Study NaltrexBuprop-3002

Dear Dr. Sharretts:

Reference is made to Nalpropion Pharmaceuticals LLC's NDA 200063 for Contrave (naltrexone HCl and bupropion HCl) Extended-Release Tablets. Reference is also made to the postmarketing requirement (PMR) outlined in the September 10, 2014, approval letter for NDA 200063.

2778-3 A clinical pharmacology (Part A) followed by a 52-week randomized, doubleblind and placebo-controlled pediatric study (Part B) under PREA to evaluate the pharmacokinetics, safety, and efficacy of Contrave (naltrexone/bupropion) for the treatment of obesity in pediatric patients ages 7-11 years (inclusive). Part B should not be initiated until the results of the adolescent pharmacokinetics, safety, and efficacy study (PMR 2778-2) have been submitted to and reviewed by the Agency.

Further reference is made to the Agency's October 8, 2024 Notice of Noncompliance letter regarding PMR 2778-3 and the subsequent Agency letter dated October 11, 2024, releasing the sponsor from the above PMR. The Agency indicated that this study is no longer needed because the product fails to represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is unlikely to be used in a substantial number of pediatric patients.

Per the PMR release letter, it is the Sponsor's understanding no further action is needed with regards to this study. A formal submissions will be made to the Contrave IND and NDA to withdraw the protocol from these applications and the updated status of PMR 2778-3 will be reported in the IND and NDA annual reports, respectively.

If you have any questions about this submission, please feel free to contact the undersigned at (949) 463-5345 or via email at achesnut@curraxpharma.com.

Sincerely,

Aaron Chesnut Digitally signed by Aaron Chesnut
Date: 2024.10.21 13:12:38 -05'00'

Aaron Chesnut
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This submission is compliant with FDA's Guideline for Industry and current eCTD specifications.

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