

## **Clinical Pharmacology and Biopharmaceutics Review**

NDA: 20,415 SE5(011)

Drug Brand Name: Remeron

Generic name: mirtazapine

Formulation: IR tablet

Strength: 15mg

Route of Administration: po

Indication: Depression

Sponsor: Organon Inc. 375 Mt. Pleasant Avenue, West Orange, NJ 07052

Type of submission: Pediatric Efficacy Supplement

Clinical Division: HFD-120/Neuropharmacological Drug Products

OCPB Division: HFD-860/DPEI

Priority: Standard

Submission Date: 05/01/2001, 08/24/2001

Primary reviewer: Wen-Hwei Chou, Pharm.D., Ph.D

Team leader: Ramana Uppoor, Ph.D.

### **Executive Summary**

In response to the Pediatric Written Request from the Agency, the sponsor submitted results from the following two clinical studies in pediatric patients (7-17 years old): (1) protocol #003-047 entitled "A single dose, pharmacokinetic trial of Remeron (mirtazapine) in children and adolescents with major depression", and (2) protocol # 003-045 entitled "A multi-center, randomized, double-blind, placebo-controlled efficacy and safety study of Remeron in outpatient children and adolescents with major depressive disorder". However, in light of the absence of the necessary information (e.g., comparative adult data and study reports, assay validation data), a meaningful pediatric labeling cannot be proposed at this time. Evaluation of the appropriateness of population pharmacokinetics in the study #003-45 is deferred, and only the single dose pharmacokinetic study (#0030047) is reviewed.

### **Recommendation**

The Office of Clinical Pharmacology and Biopharmaceutics/Division of Pharmaceutical Evaluation I has reviewed this pediatric supplement and finds the data submitted insufficient to provide any meaningful pediatric pharmacokinetic labeling.