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**Application Number 20-982
20-936/S-008**

**CLINICAL PHARMACOLOGY and
BIOPHARMACEUTICS REVIEW(S)**

MAR 1 1999

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW**NDA 20-982****Paxil CR® (Paroxetine hydrochloride)**

(12.5, 25, 37.5 and 50 mg controlled-release tablets)

Type of submission: Original NDA

Submission Date: April 22, 1998

Sponsor: Smithkline Beecham

INDICATION: Panic Disorder

REVIEWER: Rae Yuan, Ph.D.

The sponsor seeks approval for paxil CR for treating panic disorder. Reference is made to NDA 20-936 for paxil CR for the treatment of depression. The present submission consists of data from three clinical trials in patients with panic disorder and one bioequivalence study in healthy volunteers (Study 569) comparing 12.5 mg tablets developed at Cidra manufacturing site to the one at Crawley site. During the review, however, the reviewer was informed that the sponsor intends to develop the 12.5mg and 25 mg SOLELY at the Crawly, UK site (please see the attachment). Since the pharmacokinetics of the two strengths developed at Crawley have been reviewed for NDA-20936, and the clinical studies in this submission utilized these tablets, no additional information on human pharmacokinetics needs to be reviewed in this submission.

COMMENTS:

1. All the human pharmacokinetic information refers to NDA 20-936. No additional information on human pharmacokinetics is available in this submission.
2. The labeling should contain the same information on pharmacokinetics of the drug (in the Clinical Pharmacology section) for panic disorder as the ones for depression (NDA 20-936).

RECOMMENDATION:

This submission has been reviewed by OCPB. Please convey the Comments 1 to the medical officer and Comment 2 to the sponsor.

Rae Yuan, Ph.D.

Team Leader: Chandra Sahajwalla /S/ 3/1/99
Office of Clinical Pharmacology and Biopharmaceutics/Division I

CC list: HFD-120; CSO; HFD-860 (Yuan, Sahajwalla, Methu); CDR (Barbara Murphy)