CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-415/S-003

APPROVAL LETTER

NDA 20-415/S-003

Organon Inc.
Attention: Albert P. Mayo
Director, Regulatory Affairs
375 Mt. Pleasant Avenue
West Orange, New Jersey 07052

MAR 17 1997

Dear Mr. Mayo:

Please refer to your November 18, 1996, supplemental New Drug Application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Remeron (mirtazapine) 15 and 30 mg tablets.

The supplemental application provides for an additional 45 mg tablet dosage strength for your approved product, Remeron tablets.

We have completed our review of this supplemental application, and it is approved.

Additionally, please note that the same dissolution methodology and specification that were recommended for the current 15 mg and 30 mg tablets are also being extended to include the new 45 mg tablet strength. Therefore, the following dissolution method and specification will apply for all tablet strengths:

Apparatus:	U.S.P. Apparatus 2 (Paddle)
Paddle Speed:	50 RPM
Medium:	900 mL 0.1N HCL at 37 $\pm$ 0.5°C
Specification:	_____

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

If you have any questions concerning this supplemental application, please contact Mr. Paul David, Project Manager, at (301) 594-5530.

Sincerely yours,

/S/

Paul Leber, M.D.
Director
Division of Neuropharmacological
Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
NDA ORIG 20-415
HF-2/MedWatch
HFD-120/DIV File
HFD-002/ORM
HFD-92/DDM-DIAB
HFD-120/PLeber/TLaughren/AM
HFD-120/SBlum/MZarif
HFD-120/PDavid
HFD-860/RBaweja/SIbrahim
~~HFD-120/JAllen~~
HFD-222/New Drug Chemistry Division Director
DISTRICT OFFICE
03/10/97pd
DOC #REMERON\S-003-AP.LTR
SUPPLEMENTAL APPLICATION APPROVED

HFD-40
HFD-613
HFD-730