CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-415/S-003

ADMINISTRATIVE DOCUMENTS

APR 17 1997

NDA 20-415/S-003

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

Dear Mr. Mayo:

Please refer to your supplemental New Drug Application for Remeron (mirtazapine) tablets.

Reference is also made to an Agency letter dated March 17, 1997, providing for the approval of this supplemental application with draft labeling.

We acknowledge receipt of your submission dated April 3, 1997, containing final printed labeling (Label Code 5310140).

We have reviewed the labeling that you have submitted in accordance with our March 17, 1997 approval letter, and we find it acceptable.

Should you have any questions concerning this NDA, 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/AMosholder
HFD-120/PDavid
HFD-100
HFD-40 (LStockbridge)
HFD-638
HFD-730
DISTRICT OFFICE
04/14/97pd
DOC #REMERON\S-003ACK.LTR
ACKNOWLEDGE AND RETAIN LETTER
FINAL PRINTED LABELING SUBMISSION AFTER APPROVAL

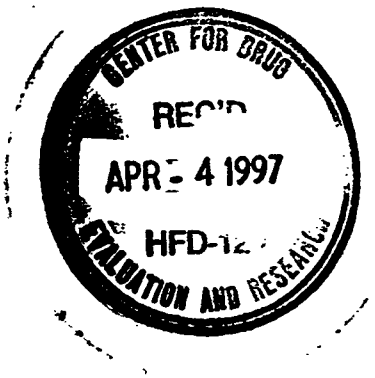
AKZO NOBEL

CONFIDENTIAL

Organon Inc.
SCS-003/FA
[illegible]

April 3, 1997

Paul Leber, M.D., Director
Division of Neuropharmacological Drug Products
Center for Drug Evaluation and Research (HFD-120)
Woodmont II Building, 4th Floor
1451 Rockville Pike
Rockville, MD 20857



Re: NDA 20-415
Remeron™ (mirtazapine) Tablets - Supplement 003
FINAL PRINTED LABELING

Dear Dr. Leber:

Reference is made to our NDA No. 20-415 for Remeron™ (mirtazapine) Tablets approved June 14, 1996 for the treatment of depression, and to our submission of S-003 dated November 18, 1996. Reference is also made to the March 17, 1997 letter of approval for this supplement, and to the March 21, 1997 teleconference between Mr. P. David of FDA, and Dr. L. Tran of Organon Inc., requesting submission of final printed labeling for the supplement.

Accordingly, we herewith provide twenty (20) copies of final printed package inserts as requested in the above-cited teleconference.

Please note that Organon Inc. regards this submission and all correspondence related thereto as confidential, trade secret and proprietary information and hereby claims protection from disclosure under the applicable sections of 18 U.S.C. and 21 CFR.

Should you have any questions regarding this submission, please contact the undersigned at 201-325-4837.

Sincerely,

Carol Shechman for

Loan Tran, Pharm. D.
Assistant Director, Regulatory Affairs

Organon

Enclosures: Twenty (20) Package Inserts (Item # 5310140, Rev. 9/96)
cc: Mr. Paul David, Project Director (letter only)
Sent via Federal Express #1870823415

Organon Inc.
375 Mt. Pleasant Avenue
West Orange
New Jersey 07052
USA
Tel.: (201) 325-4500
Fax: (201)-325-4589

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: March 17, 1997

FROM: Thomas P. Laughren, M.D. ISI
Team Leader, Psychiatric Drug Products
Division of Neuropharmacological Drug Products
HFD-120

SUBJECT: Recommendation for Approval Action for
Remeron (mirtazapine) 45 mg tablet

TO: File NDA 20-415/S-003
[Note: This memo should be filed with the 11-18-96 original submission.]

This application is for a Remeron 45 mg tablet, which is currently marketed as 15 and 30 mg tablets for the treatment of depression.

(1) This new strength has dissolution profiles comparable to the lower strengths and the same method and specifications as already approved can be extended to this new strength. The Division of Pharmaceutical Evaluation I has recommended approval of this new strength.

(2) ONDC has also recommended approval of this new strength.

(3) The only labeling change is the addition of the new strength in the Description and How Supplied sections.

Remeron is already approved at doses up to a maximum of 45 mg/day, and there are no clinical issues requiring review. Thus, I also recommend approval of this supplement.

cc:
Orig NDA 20-415/S-003
HFD-120/DivFile
HFD-120/TLaughren/PLeber/AMosholder/PDavid

DOC: NDA20415.1

MAR 11 1997

CSO LABELING REVIEW

Date of Review: March 11, 1997

NDA NUMBER: 20-415 (Tablets)
Submission Date: Original Application Approved June 14, 1996. FPL submitted on September 19, 1996, and an acknowledge/retain letter issued October 17, 1996. SCS-003 dated November 18, 1996, provides for an additional tablet strength, a 45 mg Remeron tablet

Sponsor: Organon, Inc.

Product Name: Trade Name: Remeron; Generic Name: mirtazapine; Dosage Form: tablets

Product Indication: Antidepressant

Materials Reviewed:

1. FPL submitted with the SCS-003 application.

2. FPL submitted on September 19, 1996, in response to the Agency approval letter for this NDA.

SCS-003 dated November 18, 1996
FPL LABELING (Dated 9/96); Label Code: 5310140
Reviewed by Medical Officer: No
P ...ed by Chemist: Yes
(...s Being Effected: No

This submission provides for final printed labeling identical to the FPL submitted in response to the Agency approval letter for this NDA except for the following additions:

The addition of the new strength, the 45 mg tablet, under the **DESCRIPTION** and the **HOW SUPPLIED** sections.

CONCLUSIONS & RECOMMENDATIONS:

1. The chemistry and biopharmaceutic reviewers have completed their reviews of this supplemental application, and they are recommending approval.

2. The FPL submitted only provides for the changes noted above.

3. I recommend that an approval letter issue for this supplemental application.

/S/

Paul A. David, R.Ph.
Project Manager

/S/

John Purvis
Project Management Supervisor

ORIG NDA 20-415
HFD-120/DIV FILE
LABELING REVIEW

AKZO NOBEL

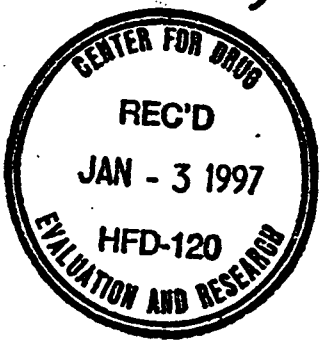
CONFIDENTIAL

ORIGINAL

Organon Inc.

January 2, 1997

NDA SUPPL AMEND
SCS-003
(BC)



Paul Leber, M.D., Director
Division of Neuropharmacological Drug Products
Center for Drug Evaluation and Research (HFD-120)
Woodmont II Building, 4th Floor
1451 Rockville Pike
Rockville, MD 20857

Re: NDA 20-415
REMERON™ (mirtazapine) Tablets
Supplement 003, Additional Dosage Strength
Response to Request for Additional Information

Dear Dr. Leber:

Reference is made to Organon Inc. NDA 20-415 for Remeron™ (mirtazapine) Tablets and to supplement S-003 submitted November 17, 1996 providing for an additional dosage strength, Remeron™ 45 mg tablets. Reference is further made to teleconference on December 5, 1996 during which Dr. M. Zarifa, Reviewing Chemist, requested copies of executed batch record for a lot of Remeron™ 45 mg tablets submitted in the SNDA and if possible a full production scale ——— ts) record. Because a full production batch of Remeron 45 mg tablets has not yet been manufactured and because the ——— ——— across all Remeron™ tablet strengths, Dr. Zarifa requested an executed batch record of a production batch of Remeron™ 15 mg or 30 mg tablets which would demonstrate the manufacture of a ———

Accordingly, we herewith provide the following executed batch records:

- Remeron™ 45 mg tablet, batch 08495001 ———
- Remeron™ 30 mg tablet, batch 117847001 ———

As discussed and agreed to be acceptable with Dr. Zarifa, these are actual production records therefore they are in Dutch. For reference, please refer to the English translated master batch record (unexecuted) provided in the SNDA.

Organon

Organon Inc.
375 Mt. Pleasant Avenue
West Orange
New Jersey 07052
USA
Tel.: (201) 325-4500
Fax: (201)-325-4589

Please note that Organon Inc. regards this application and all correspondence related thereto as confidential, trade secret and proprietary information and hereby claims protection from disclosure under the applicable sections of 18 U.S.C. and 21 CFR.

Should you have any questions regarding this submission, please contact the undersigned at (201) 325-4837.

Sincerely,

Loan T. Tran, Pharm. D.
Assistant Director
Regulatory Affairs

cc: Mr. Paul David, Project Director (letter only)
Submitted in Duplicate to NDA 20-415
via Airborne Express Airbill No. 3348273-036

341

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date NOV 27 1996

NDA No. 20-415

Organon Inc.
375 Mt. Pleasant Avenue
West Orange, New Jersey 07052

Attention: Loan Tran

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: **REMERON-TABLETS**

NDA Number: 20-415

Supplement Number: S-003

Date of Supplement: November 18, 1996

Date of Receipt: November 19, 1996

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on January 18, 1997 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Neuropharmacologic Drug Products
Attention: Document Control Room
5600 Fishers Lane, HFD-120
Rockville, MD 20857

Sincerely yours,

/S/

(FOR) John Purvis

Chief, Project Management Staff
Division of Neuropharmacologic Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

AKZO NOBEL

CONFIDENTIAL

ORIGINAL Organon Inc.

NDA NO 20-415 REF. NO. SCS-003

NDA SUPPL FOR Controls

NDA SUPPLEMENT

November 18, 1996

Paul Leber, M.D., Director
Division of Neuropharmacological Drug Products
Center for Drug Evaluation and Research (HFD-120)
Woodmont II Building, 4th Floor
1451 Rockville Pike
Rockville, MD 20857

Re: NDA 20-415
Remeron™ (mirtazapine) Tablets
Supplement 003: Additional Dosage Strength

Dear Dr. Leber:

Reference is made to our NDA No. 20-415 for Remeron™ (mirtazapine) Tablets approved June 14, 1996 for the treatment of depression. The usual effective dose range is 15 mg - 45mg per day, and it is available as 15 mg and 30 mg tablets. The purpose of this supplemental New Drug Application (SNDA) is to provide for an additional dosage strength for the product, Remeron™ 45 mg tablets.

The SNDA provides for chemistry, manufacturing and controls information on the production and packaging of the Remeron™ 45 mg tablets. Additionally, 4 copies of the draft revised package insert (changes to include the 45 mg tablets are highlighted) and 16 copies of final printed container/carton labels are provided.

In accordance with 21CFR 314.70(a), an identical copy field copy of this supplement has been prepared for simultaneous submission to the Newark District Ofice of the FDA. The undersigned hereby certifies, to the reviewing division and to the Newark District Office, that the copy submitted to the district office is a true copy of that submitted to FDA headquarters.

11/25/96
medical officer Note
There is no new clinical data in this supplement. The revised package insert is acceptable from a clinical standpoint.
LS

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
NOV 19 1996
HFD-120

Organon

Organon Inc.
375 Mt. Pleasant Avenue
West Orange
New Jersey 07052
USA
Tel.: (201) 325-4500
Fax: (201)-325-4589

Please note that Organon Inc. regards this submission and all correspondence related thereto as confidential, trade secret and proprietary information and hereby claims protection from disclosure under the applicable sections of 18 U.S.C. and 21 CFR.

Should you have any questions regarding this submission, please contact the undersigned at 201-325-4837.

Sincerely,

for Loan Tran, Pharm. D.
Assistant Director, Regulatory Affairs
Enclosures: Form 356h
Volumes 1, 2

cc: Mr. Paul David, Project Director (2 desk copies)

Submitted in duplicate to NDA 20-514
Via Fedex Airbill No. 9134949062

Copy to:

FDA North Brunswick Residence
120 North Center Drive, Bldg. C
New Brunswick, NJ 08902

via Federal Express Airbill No. 1870823264

CDER FOI CONTROL RECORD

Contrl No.: F99-11082
Requestor:
FOI SERVICES INC
11 FIRSTFIELD RD
GAITHERSBURG MD 20878-1703

Request Date:
FDA Recd Date: 13-MAY-1999
CDER Recd Date: 13-MAY-1999
Due Date: 11-JUN-1999

Request Type: COMMERCIAL

CDER Subject:
ORGANON - REMERON (MIRTAZAPINE 45MG TAB) APRVL RECS

----- FDA FOI Routing Offices -----

Office		Date Assigned	Status
HFD205	CENTER DRUG EVALUATION &	12-MAY-1999	PA PENDING ACTION

----- CDER FOI Routing Offices -----

Office	Date Referred	Action Taken
~~120~~	~~13-MAY-1999~~ Closed 8/9/04	
~~RR024~~	~~09-AUG-2004~~	

Direct Response Date: Completed 8/12/04 (V.S.)

Interim Date: _____

Withdrawal Date: _____

Routing Instructions: completed 8/16/04 (V.S.)

Fiche: _____

Dupe Of: _____

N 20-415/S-003CS 11-18-96 AP 3-17-97
1-2-97 " "

AP 3/17/97

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**
Center for Drug Evaluation and Research
Office of Regulatory Policy
Division of Information Disclosure Policy
5600 Fishers Lane, HFD-13
Rockville, Maryland 20857

August 16, 2004

In Response Refer to File: F99-11082
Your control number: 160968

FOI Services, Inc.
11 Firstfield Road
Gaithersburg, MD 20878-1704

To Whom It May Concern:

This is in response to your request of May 11, 1999 in which you requested a copy of approval documents for NDA 20-415/S-003 for Remeron. Your request was received in the Center for Drug Evaluation and Research on May 13, 1999.

The documents you have requested are enclosed.

The following charges may be included in a monthly invoice:
Reproduction: 4.40 Search: 27.00 Review: 43.00 Other: 0.00 Total: 74.40

The above total may not reflect final charges for this request.

PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE FOR THE TOTAL MONTHLY FEE.

If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number.

This concludes the response for the Center for Drug Evaluation and Research. If I can be of further assistance to you, please do not hesitate to contact me at (240) 453-6691.

Sincerely,

Darshini Satchi
Darshini Satchi
Regulatory Counsel
Office of Regulatory Policy
Division of Information Disclosure Policy, HFD-13

Enclosure: 44 pages 20-415/S-003

foi

FOI Services, Inc.
11 Firstfield Road
Gaithersburg MD 20878-1703 USA
Phone: 301-975-9400
Fax: 301-975-0702

FOOD & DRUG ADMINISTRATION
FREEDOM OF INFORMATION STAFF
5600 FISHERS LANE
ROCKVILLE, MD 20857

5/11/99

CONTROL NUMBER 160968

A120

PURSUANT TO THE PROVISIONS OF THE FREEDOM OF INFORMATION ACT, PLEASE PROVIDE US WITH A PAPER COPY (PREFERABLY NOT MICROFICHE) OF THE FOLLOWING DOCUMENTS. IF THE COST OF PROVIDING THESE DOCUMENTS WILL EXCEED 100.00, PLEASE CALL US FIRST FOR AUTHORIZATION OF THE CHARGES, UNLESS INDICATED OTHERWISE BELOW.

PLEASE REFER TO OUR CONTROL NUMBER IN YOUR REPLY.

ATTN: CENTER FOR DRUGS

COPY OF THE DISCLOSABLE APPROVAL DOCUMENTATION FOR REMERON (MIRTAZAPINE) 45 MG TABLET MANUFACTURED BY ORGANON, APPROVED 3/97.

99-11082

RECEIVED
MAY 13 1999
FDA FOI STAFF (HFI-35)

HFD205 - (F)
RL

CDER FOI CONTROL RECORD

Contrl No.: F01-14742
Requestor:
FOI SERVICES INC
11 FIRSTFIELD RD
GAITHERSBURG MD 20878-1704

Request Date:
FDA Recd Date: 22-AUG-2001
CDER Recd Date: 23-AUG-2001
Due Date: 20-SEP-2001

Request Type: COMMERCIAL

CDER Subject:
ORGANON - REMERON (MIRTAZAPINE) NDA 20-415/S-003 APRVL RECS

----- FDA FOI Routing Offices -----

Office		Date Assigned	Status
HFD13	Code transl. unavailable	22-AUG-2001	PA PENDING ACTION

----- CDER FOI Routing Offices -----

Office	Date Referred	Action Taken
~~120~~	~~23-AUG-2001~~ Chael 8/5/04 SG	
~~HFD24~~	~~07-AUG-2004~~	

Direct Response Date: 8/16/04

Interim Date: _____

Withdrawal Date: _____

Routing Instructions: Completed 8/16/04 D.S.

Fiche: _____

Dupe Of: _____

N020-415/S-003
AP 3-17-97

11-18-96 AP 3-17-97
1-2-97 " "

DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**
Center for Drug Evaluation and Research
Office of Regulatory Policy
Division of Information Disclosure Policy
5600 Fishers Lane, HFD-13
Rockville, Maryland 20857

August 16, 2004

In Response Refer to File: F01-14742
Your control number: 5203502

FOI Services, Inc.
11 Firstfield Road
Gaithersburg, MD 20878-1704

To Whom It May Concern:

This is in response to your request of August 20, 2001 in which you requested a copy of approval documents for NDA 20-415/S-003 for Remeron. Your request was received in the Center for Drug Evaluation and Research on August 22, 2001.

The documents you have requested are enclosed.

The following charges may be included in a monthly invoice:
Reproduction: 4.40 Search: 27.00 Review: 43.00 Other: 0.00 Total: 74.40

The above total may not reflect final charges for this request.

PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE FOR THE TOTAL MONTHLY FEE.

If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number.

This concludes the response for the Center for Drug Evaluation and Research. If I can be of further assistance to you, please do not hesitate to contact me at (240) 453-6691.

Sincerely,

Darshini Satchi
Darshini Satchi
Regulatory Counsel
Office of Regulatory Policy
Division of Information Disclosure Policy, HFD-13

Enclosure: 44 pages 20-415/S-003

foi

FOI Services, Inc.
11 Firstfield Road
Gaithersburg MD 20878-1704
Phone: 301-975-9400
Fax: 301-975-0702

August 20, 2001

FOOD & DRUG ADMINISTRATION
FREEDOM OF INFORMATION STAFF
5600 FISHERS LANE
ROCKVILLE, MD 20857

Please Refer To Our Control Number: 5203502

120

Pursuant to the provisions of the Freedom of Information Act, please provide us with a paper copy, (preferably not microfiche) of the following documents:

Attention: Center for Drugs

Copy of the disclosable approval information for S-003 to NDA# 20-415, for Remeron (mirtazapine), manufactured by Organon.

If the cost of providing these documents will exceed $150.00, please call us first for authorization of the charges unless indicated otherwise above.

Please refer to our control number above in your reply.

01-14742

RECEIVED
AUG 22 2001
FDA DIV FOI(HFI-35)

HFD-13(FOIBR)