

CONFIDENTIAL

Lisa Rarick, MD, Director (DRUDP)
October 28, 1999
Page 2

The following files are provided on one (1) diskette in Attachment 2 for CTR 99 Tablets:

- Brief Summary Patient Package Insert.doc
- Detailed Patient Package Insert.doc
- Package Insert.doc
- 092003.wpd

Should you require additional information, please do not hesitate to contact the undersigned at (973) 325-5285.

Sincerely,



Giselle Rose
Manager, Regulatory Affairs

GR/cjw

Desk Copy: Ms. Jennifer Mercier, HFD-580 (2)

Form FDA 356h
Attachments

Sent in Duplicate
via Federal Express Airbill No. 810494763825

**APPEARS THIS WAY
ON ORIGINAL**



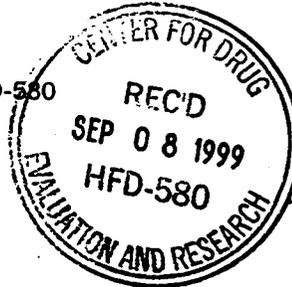
ORIGINAL
ORIG AMENDMENT
SV

Organon Inc.

September 2, 1999

CONFIDENTIAL

Lisa Rarick, MD, Director
Division of Reproductive and Urologic Drug Products, HFD-580
Center for Drug Evaluation and Research
Food and Drug Administration
Attn: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857



**NDA 21-090 CTR 77 (desogestrel and ethinyl estradiol) Tablets
120-Day Safety Update**

Dear Dr. Rarick:

Reference is made to our pending New Drug Applications NDA 21-090 for CTR 77 (desogestrel and ethinyl estradiol) Tablets submitted on May 7, 1999

Reference is also made to the proposal dated June 16, 1999 for the format and content of the safety update reports. Finally, reference is made to the telephone conversation of July 1, 1999 between Ms. Jennifer Mercier, Project Manager, of your Division and Ms. Giselle Rose, Organon Regulatory Affairs, regarding FDA's acceptance of the proposal of one safety update for both NDAs consisting of a cross-reference to our other marketed oral contraceptive products, Mircette™ and Desogen®. In accordance with 21 CFR §314.50(d)(5)(vi)(b)(1), we herewith submit the update of safety data.

Clinical studies with CTR 77 and CTR 99 Tablets were completed in February 1996. There are no ongoing clinical studies at this time. All available information about the safety of these products was reported in the Integrated Summary of Safety in their respective NDAs. Therefore, we hereby authorize the Agency to refer to NDA 20-713 for Mircette™ (desogestrel/ethinyl estradiol and ethinyl estradiol) Tablets and to NDA 20-071 for Desogen® (desogestrel and ethinyl estradiol) Tablets specifically for the review of relevant safety information.

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

Should you have any questions regarding this submission, please contact the undersigned at (973) 325-4830 or Ms. Giselle Rose at (973) 325-5285.

Sincerely,

Thomas L. Pituk

Thomas L. Pituk, PhD
Associate Director, Regulatory Affairs

GR/cjw

Sent via Certified Mail No. Z-073-592-666

NAI 9/13 @

REVIEWS COMPLETED
CSO ACTION:
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CSO INITIALS <i>MA</i> DATE <i>9/13/99</i>



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



CONFIDENTIAL

Organon Inc.

August 24, 1999

NC

Lisa Rarick, M.D., Director
Division of Reproductive and Urologic Drug Products, HFD-580
Center for Drug Evaluation and Research
Food and Drug Administration
Attn: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857



NDA 21-090 CTR 77 (desogestrel and ethinyl estradiol) Tablets

**General Correspondence: Request for Full Waiver for
Pediatric Use Information**

Dear Sir/Madam:

Reference is made to NDA 21-090 for CTR 77 (desogestrel and ethinyl estradiol) Tablets submitted on May 7, 1999

Reference is also made to the telephone conversation of August 19, 1999 between the undersigned and Ms. Jennifer Mercier, Project Manager, of your Division informing Organon that pediatric studies will not be needed as required by 21 CFR 314.55.

As requested by Ms. Mercier, and pursuant to 21 CFR 314.55(c)(2), we hereby request a full waiver of the requirements for adequate data to assess the safety and effectiveness of the drug products for the claimed indication in all pediatric subpopulations.

Should you have any questions or comments regarding this request, please do not hesitate to contact the undersigned at (973) 325-5285.

Sincerely,

Giselle Rose

Giselle Rose
Manager, Regulatory Affairs

NAI
JMY
8/20/99

GR:bl



Form FDA 356h
Submitted in duplicate
via Federal Express Airbill # - 810494762932

Organon Inc.
375 Mt. Pleasant Avenue
West Orange
New Jersey 07052
USA
Tel.: (973) 325-4500

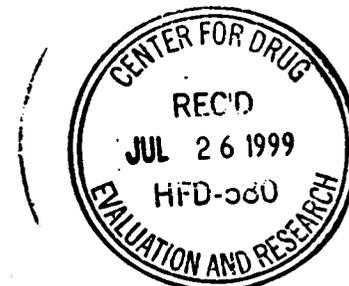
ORIGINAL
ORIG AMENDMENT
AKZO NOBEL

CONFIDENTIAL

Organon Inc.

July 23, 1999

Lisa Rarick, M.D., Director
Division of Reproductive and Urologic Drug Products, HFD-580
Center for Drug Evaluation and Research
Food and Drug Administration
Attn: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857



**NDA 21-090 CTR 77 (desogestrel and ethinyl estradiol) Tablets
Amendment: Chemistry, Manufacturing and Controls Information**

Dear Sir/Madam:

Reference is made to NDA 21-090 for CTR 77 (desogestrel and ethinyl estradiol) Tablets submitted on May 7, 1999. In a submission to IND 45,548 on December 18, 1998 (Submission Serial No. 045), Organon proposed the primary stability package to include stability data generated using the second set of commercial scale validation batches (one batch per strength) to be submitted within 120 days after NDA submission. In correspondence dated March 1, 1999, FDA accepted the proposal although requested some stability data from this second set of commercial scale validation batches be provided at the time of NDA submission.

A report containing up to 18 months stability data from the second set of commercial scale validation batches was submitted in the original NDA application. As committed, we hereby amend the NDA within 120 days of submission to provide for the following supporting documentation for these batches:

- Certificates of Analysis for drug substance (desogestrel and ethinyl estradiol) used
- Certificates of Analysis for inactive components used
- Production Batch Records (original Dutch versions and certified English translations)
- Certificates of Analysis for drug product

In accordance with 21 CFR 314.70(a), an identical field copy of this Amendment (1 volume) has been prepared for simultaneous submission to the District Office of the FDA in North Brunswick, New Jersey.

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

The Organon logo, consisting of the word "Organon" in a stylized font inside an oval shape.

Organon Inc.
375 Mt. Pleasant Ave
West Orange
New Jersey 07052
USA
Tel : (973) 325-4500

CONFIDENTIAL

Lisa Rarick, M.D., Director (DRUDP)
July 23, 1999
Page 2

Should you have any questions or comments regarding this submission, please do not hesitate to contact the undersigned at (973) 325-4833 or Giselle Rose at (973) 325-5285

Sincerely,



Thomas L. Pituk, PhD
Associate Director
Regulatory Affairs

GR:bl

Form FDA 356h
Enclosures

Sent via Federal Express Airbill No 810494763479

Copy to: District Office
Food and Drug Administration
120 North Center Drive, Bldg. C
North Brunswick, NJ 08902

Sent via Federal Express Airbill No. 810494763480

REVIEWS COMPLETED	
CSO ACTION:	
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CSO INITIALS	DATE

**APPEARS THIS WAY
ON ORIGINAL**

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NEW CORRESP

VL



AKZO NOBEL

CONFIDENTIAL

Organon Inc.

July 2, 1999

Lisa Rarick, M.D., Director
Division of Reproductive and Urologic Drug Products, HFD-580
Center for Drug Evaluation and Research
Food and Drug Administration
Attn: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857



NDA 21-090 CTR 77 (desogestrel and ethinyl estradiol) Tablets

General Correspondence: Request for Partial Waiver for Pediatric Use Information

Dear Sir/Madam:

Reference is made to NDA 21-090 for CTR 77 (desogestrel and ethinyl estradiol) Tablets submitted on May 7, 1999

Pursuant to 21 CFR 314.55(c)(3)(i), we hereby request a partial waiver of the requirements for adequate data to assess the safety and effectiveness of the drug products for the claimed indication in all pediatric subpopulations except for the 12-17 age group based on the certification that use of the drug product before menarche is not indicated.

As required, plans for assessment of the safety and effectiveness of the products in the 12-17 year old subgroup for both CTR 77 and CTR 99 Tablets will be forwarded under separate cover within 120 days from the date of the FDA acknowledgment letter for CTR 77 Tablets (Attachment 1) no later than September 12, 1999.

Should you have any questions or comments regarding this request, please do not hesitate to contact the undersigned at (973) 325-5285.

Sincerely,

Giselle Rose

Giselle Rose
Manager
Regulatory Affairs

GR:bl

Form FDA 356h
Attachment

submitted in duplicate
via Federal Express Airbill # - 810429891764

8/6/99
Reviewed
Givento
CSO for
response
BSG

REVIEWS COMPLETED	
CSO ACTION:	
<input type="checkbox"/> LETTER	<input type="checkbox"/> N.A.I. <input type="checkbox"/> MEMO
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ORIGINAL



ORIG AMENDMENT

CONFIDENTIAL

AKZO NOBEL

Organon Inc.

July 1, 1999

Lisa Rarick, M.D., Director
Division of Reproductive and Urologic Drug Products, HFD-580
Center for Drug Evaluation and Research
Food and Drug Administration
Attn: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857



*I made
the review
2/22/00*

NDA 21-090 CTR 77 (desogestrel and ethinyl estradiol) Tablets

Response to FDA Request for Information

Dear Sir/Madam:

Reference is made to NDA 21-090 for CTR 77 (desogestrel and ethinyl estradiol) Tablets submitted on May 7, 1999

Reference is also made to the telephone conversation between Ms. Jennifer Mercier and the undersigned on June 25, 1999 requesting the following information to be submitted to facilitate the review of the above referenced NDAs.

1. Publications regarding the metabolism of desogestrel referenced in the Annotated Labeling.

The following publications submitted as Phase 4 Commitments to NDA No. 20-713 and IND No. 43,289 (Submission Serial No. 036) for Mircette™ (desogestrel/ethinyl estradiol and ethinyl estradiol) Tablets on April 19, 1999 are provided in Attachment 1:

- Verhoeven CHJ, Krebbers SFM, Wagenaars GN, et al.
In vitro and *in vivo* metabolism of desogestrel in several species.
Drug Metabolism and Disposition 26(9):927-936, 1998.
- Gentile DM, Verhoeven CHJ, Tsutomu S, et al.
The role of CYP2C in the *in vitro* bioactivation of the contraceptive steroid desogestrel.
The Journal of Pharmacology and Experimental Therapeutics 287(3):975-982, 1998.
- Gentile DM, Krebbers SFM, Verhoeven CHJ, et al.
CYP3A4 is responsible for the metabolism of etonogestrel *in vitro*.
Unpublished manuscript.



REVIEWS COMPLETED	
CSO ACTION:	
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CSO INITIALS	DATE

Organon Inc
375 Mt Pleasant Aven
West Orange
New Jersey 07052
USA
Tel 1973 325-4500

Lisa Rarick, M.D., Director (DRUDP)
July 1, 1999
Page 2

CONFIDENTIAL

2. Item 6. Human Pharmacokinetics and Bioavailability Summary with accompanying tables and graphs in electronic format.

The following files are provided on one (1) zip disk for NDA 21-090 for CTR 77 Tablets in Attachment 2:

- Human Pharmacokinetics and Bioavailability Summary: humpkb.doc (MS Word)
- Core Report of Study 092004: 092004.pdf (Adobe Acrobat)
- Core Report of Study 092005: 092005.pdf (Adobe Acrobat)
- Core Report of Study 092006: 092006.pdf (Adobe Acrobat)

The following files are provided on one (1) zip disk for _____ Tablets in Attachment 3:

These disks have been checked for viruses using McAfee Virus Scan for Windows Version 4.02. Please note that the NDA summary documents were provided to DRUDP on CD-ROM in their respective original applications.

Additionally, financial disclosure information for _____) is provided in Attachment 4. This information, identical to the information included in NDA 21-090 (CTR 77 Tablets), was inadvertently omitted from _____. We apologize for any inconvenience this may have caused.

Should you require additional information, please do not hesitate to contact the undersigned at (973) 325-5285.

Sincerely,



Giselle Rose
Manager, Regulatory Affairs

GR/

Desk Copy: Ms. Jennifer Mercier, HFD-580

Form FDA 356h
Attachments

Sent via Federal Express Airbill No. 810429891878

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AKZO NOBEL



ORIGINAL
NEW CORRESP
NC
Organon Inc.

June 16, 1999

Lisa Rarick, M.D., Director
Division of Reproductive and Urologic Drug Products, HFD-580
Center for Drug Evaluation and Research
Food and Drug Administration
Attn: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857



CONFIDENTIAL

NDA 21-090 CTR 77 (desogestrel and ethinyl estradiol) Tablets

General Correspondence: Proposal for 120-Day Safety Update

Dear Sir/Madam:

Reference is made to NDA 21-090 for CTR 77 (desogestrel and ethinyl estradiol) Tablets (0.100 mg DSG/0.025 mg EE, 0.125 mg DSG/0.025 mg EE, 0.150 mg DSG/0.025 mg EE, placebo) submitted on May 7, 1999 and

In accordance with 21 CFR §314.50(d)(5)(vi)(b), we herewith submit a proposal for the safety update reports.

Clinical studies with CTR 77 and CTR 99 Tablets were completed in February 1996. All available information about the safety of these products was reported in the Integrated Summary of Safety in their respective NDAs. Since the NDAs for CTR 77 Tablets were filed within 3 weeks of each other, the triphasic regimens are similar, the products are not marketed in any country and there are no ongoing clinical trials studies with either product, we propose one safety update for both NDAs consisting of a cross-reference to our other marketed oral contraceptive products, NDA 20-713 for Mircette™ (desogestrel/ethinyl estradiol and ethinyl estradiol) Tablets (0.150 mg DSG/0.020 mg EE and 0.010 mg EE) and NDA 20-071 for Desogen® (desogestrel and ethinyl estradiol) Tablets (0.150 mg DSG/0.030 mg EE).

We appreciate the Division's consideration of our proposal and respectfully request a response by the end of July. Should you have any questions or comments regarding this proposal, please do not hesitate to contact Giselle Rose at (973) 325-5285.

Sincerely,

Thomas L. Pituk, Ph.D.
Associate Director, Regulatory Affairs

GR/cjw

Sent via Certified Mail No. P-484-049-865

7/1 - will clear with M. Mann

SI

REVIEWS COMPLETED	
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CSO INITIALS	DATE



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



ORIGINAL

NEW CORRESP

Organon Inc.

May 14, 1999

Submitted to LNC for review on 6/11/99 DTL 6/11/99

CONFIDENTIAL

Lisa Rarick, M.D., Director
Division of Reproductive and Urologic Drug Products
Center for Drug Evaluation and Research (HFD-580)
Office of Drug Evaluation II
Document Control Room 17B45
5600 Fishers Lane
Rockville, Maryland 20857



NDA 21-090
CTR 77 (desogestrel and ethinyl estradiol) Tablets
General Correspondence

Dear Dr. Rarick:

Reference is made to our Original New Drug Application NDA No. 21-090 for CTR 77 (desogestrel and ethinyl estradiol) Tablets submitted on May 7, 1999. We herewith submit Cyclessa as the trademark name for CTR 77 (desogestrel and ethinyl estradiol) Tablets and request that this trade name be officially submitted to the CDER Nomenclature and Labeling Review Committee for review and approval at their next regularly scheduled meeting. To assist in the review of the proposed trade name, the following information is provided:

Proposed Trade Name:	Cyclessa
Generic Name:	desogestrel (DSG) and ethinyl estradiol (EE)
Code Name:	CTR 77
Dosage Form:	tablets
Dosage Strengths:	0.100 mg DSG/0.025 mg EE, 0.125 mg DSG/0.025 mg EE, 0.150 mg DSG/0.025 mg EE, placebo
Route of Administration:	oral
Proposed Indication:	prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception

Please advise the undersigned when the proposed trade name will be discussed by the CDER Nomenclature and Labeling Review Committee.

Should you require additional information or have any questions regarding this request, please contact Giselle Rose at (973) 325-5285.

Sincerely,

Albert P. Mayo
Executive Director, Regulatory Affairs

APM/cjw

Submitted via Federal Express Airbill No. 810429893414

REVIEWS COMPLETED	
CSO ACTION:	
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CSO INITIALS	DATE



Organon Inc.
375 Mt. Pleasant Ave.
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New Jersey 07052
USA
Tel: (973) 325-4500
Fax: (973) 325-4580

CONFIDENTIAL

**CTR 77
(desogestrel and ethinyl estradiol) Tablets**

NDA No. 21-090



Organon Inc.

May 7, 1999

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Park Building, Room 214
12420 Parklawn Drive
Rockville, Maryland 20852

CONFIDENTIAL

**NDA 21-090
CTR 77 (desogestrel and ethinyl estradiol) Tablets
Original New Drug Application**

Dear Sir/Madam:

Pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act and 21 CFR 314.50, we hereby submit in duplicate an original New Drug Application for CTR 77 (desogestrel and ethinyl estradiol) Tablets for the indication of oral contraception. CTR 77 Tablets provide 28-day oral contraception in a triphasic regimen consisting of 7 light yellow tablets containing 0.100 mg desogestrel/0.025 mg ethinyl estradiol (Days 1-7), 7 orange tablets containing 0.125 mg desogestrel/0.025 mg ethinyl estradiol (Days 8-14), 7 red tablets containing 0.150 mg desogestrel/0.025 mg ethinyl estradiol (Days 15-21), and 7 green placebo tablets (Days 22-28).

Desogestrel and ethinyl estradiol are currently approved in combination for use in oral contraception and marketed under the trade names Desogen® and Mircette™. As such, we hereby incorporate by cross-reference pertinent sections of the following applications on file with the Agency:

NDA 20-071 Desogen® (desogestrel and ethinyl estradiol) Tablets

NDA 20-713 Mircette™ (desogestrel/ethinyl estradiol and ethinyl estradiol) Tablets

IND 43,289 CTR 25 (desogestrel/ethinyl estradiol and ethinyl estradiol) Tablets
IND 45,548 CTR 77 (desogestrel and ethinyl estradiol) Tablets



Organon Inc.
375 Mt. Pleasant Avenue
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Tel.: (973) 325-4500
Fax: (973) 325-4589

NDA 21-090
CTR 77 (desogestrel and ethinyl estradiol) Tablets
Original New Drug Application
May 7, 1999
Page 2

CONFIDENTIAL

We also reference communications between the Division of Reproductive and Urologic Drug Products (DRUDP) and Organon Inc. with respect to the following agreements:

Pre-NDA clinical teleconference with DRUDP on May 18, 1998

- Prior pre-NDA discussions and agreements with the Division of Metabolic and Endocrine Drug Products on May 16, 1995 (clinical and preclinical) were reviewed.
- Nonclinical section of the NDA would consist only of a cross-reference to the nonclinical sections of Desogen® (CTR 04) NDA 20-071 (IND 32,489) and _____
- Human Pharmacokinetics and Bioavailability and Clinical Pharmacology Summaries would report the findings of the steady state study 092004 and the two bioavailability studies 092005 and 092006 for the high and low doses. Additionally, as requested by Dr. J. Hunt, a cross-study comparison of the steady state pharmacokinetics data of CTR 77 and CTR 99 would be provided in order to demonstrate any similarities or differences between the two products.
- Controlled Clinical Summary would comprise the final study reports for each of the two Phase III studies (092001 and 092002).
- Six studies conducted | _____ would be considered as Other Studies.
- Integrated Summary of Safety would consist of an integrated analysis of the two Phase III studies as well as separate presentations of the PK, bioavailability and other studies.
- Integrated Summary of Effectiveness would comprise an integrated analyses of the two Phase III pivotal studies with the exclusion of data from one investigator (Dr. R. Fiddes) to be reported separately in an addendum to the ISE. For the purposes of full disclosure Dr. Fiddes data would be included in the ISS. ✓
- Item 11 (Case Report Tabulations; CRTs) and Item 12 (Case Report Forms [for any deaths, dropouts, and pregnancies]; CRFs) would be submitted in electronic format as Adobe Acrobat PDF files according to FDA's "Guidance for Industry: Archiving Submissions in Electronic Format - NDAs" (September 1997). These items will be submitted as CD ROMs directly to the CDER Central Document Room, to be used as both the archival and the review copies of these items in the submission.

Pre-NDA CMC teleconference with DRUDP on August 18, 1998

- Prior pre-NDA discussions and agreements with the Division of Metabolic and Endocrine Drug Products on October 17, 1995 were reviewed with respect to bioequivalence, stability and validation proposals.

February 11, 1999 telephone conversation with Ms. Christina Kish

- Clarified the CRTs/CRFs to be submitted as previously discussed or in accordance with the new "Guidance for Industry: Providing Regulatory Submissions in Electronic Format - NDAs" issued (January 1999). Ms. Kish stated that either guidance may be followed. Items 11 and 12 are hereby provided in PDF Format as originally proposed.

NDA 21-090
CTR 77 (desogestrel and ethinyl estradiol) Tablets
Original New Drug Application
May 7, 1999
Page 3

CONFIDENTIAL

Therefore, this NDA submission is provided in paper (123 volumes) and electronic format. Electronic files are supplied on 4 CD-ROMS (total file size is 2.2 GB). CD-ROMs were checked for viruses using McAfee Virus Scan for Windows Version 4.02. Domain files (data listings) are provided for two Phase III studies (092001 and 092002), the steady state study (092004) and the two bioavailability studies (092005 and 092006). Patient profiles (CRTs) are provided for Studies 092001 and 092002. CRFs are provided for all subjects with narratives in Studies 092001, 092002, 092004, and 092005. There were no dropouts in Study 092006. Additionally, the core reports of the NDA summary documents (Microsoft Word, Version 7.0a for Windows 95) are provided to DRUDP on 1 CD-ROM.

FDA correspondence dated January 22, 1999

- Granted a waiver for an in vivo bioavailability study for the intermediate strength of CTR 77. The bioavailability studies for the low and high strengths as well as the dissolution data are provided in this application.

FDA correspondence dated March 1, 1999

- Accepted proposed primary stability package of 18 months data generated using the second set of commercial scale validation batches (one batch per strength) to be submitted within 120 days after submission of the NDA. However, some data from this second commercial scale batch are provided herein as requested by Dr. Lin. Supporting documentation for these batches will be submitted as an amendment during the course of review and within 120 days of this submission as originally proposed.

FDA correspondence dated March 31, 1999

- Granted a waiver for an in vivo bioequivalence study. In vitro dissolution data are provided herein.

In accordance with 21 CFR 314.70(a), an identical field copy of the Chemistry, Manufacturing and Controls section of this NDA has been prepared for simultaneous submission to the District Office of the FDA in North Brunswick, New Jersey.

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

CONFIDENTIAL

CTR 77
(desogestrel and ethinyl estradiol) Tablets

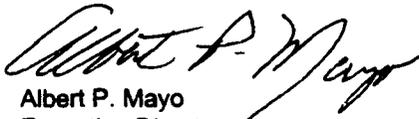
NDA No. 21-090

NDA 21-090
CTR 77 (desogestrel and ethinyl estradiol) Tablets
Original New Drug Application
May 7, 1999
Page 4

CONFIDENTIAL

We believe that the enclosed NDA is complete and well-organized to facilitate your review. Should you have any questions or comments regarding this submission, please do not hesitate to contact the undersigned at (973) 325-4833.

Sincerely,



Albert P. Mayo
Executive Director
Regulatory Affairs

GR:

HAND DELIVERED
Enclosures
Form FDA 356h

Archival Copy, Volumes 1.1 to 1.123
Chemistry Review Copy, Volumes 1.1 to 1.14
Pharmacology Review Copy, Volumes 1.1, 1.3, 1.15
Biopharmaceutics Review Copy, Volumes 1.1, 1.3, 1.16 to 1.31
Medical Review Copy, Volumes 1.1 to 1.3, 1.32 to 1.100, 1.102 to 1.123
Biostatistics Review Copy, Volumes 1.1, 1.3, 1.32 to 1.122

Cover Letter to:

Ms. Jennifer Mercier, HFD-580

Copy to:

District Office, Volumes 1.3 to 1.14
Food and Drug Administration
120 North Center Drive, Bldg. C
North Brunswick, NJ 08902



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-090

Organon, Inc.
Attention: Albert Mayo
Executive Director, Regulatory Affairs
375 Mt. Pleasant Avenue
West Orange, NJ 07052

Dear Mr. Mayo:

We acknowledge receipt on October 20, 2000 of your October 19, 2000 resubmission to your new drug application (NDA) for Cyclessa™ (desogestrel/ethinyl estradiol) Tablets.

This resubmission contains additional labeling information submitted in response to our March 7, 2000 action letter.

We consider this a complete Class 1 response to our action letter. Therefore, the user fee goal date is December 20, 2001.

If you have any questions, call Jennifer Mercier, Regulatory Project Manager, at 301-827-4260.

Sincerely,

Terri Rumble
Chief, Project Management Staff
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Mercier

NDA 21-090

INFORMATION REQUEST LETTER

Organon, Inc.
Attention: Thomas Pituk, Ph.D.
Associate Director, Regulatory Affairs
375 Mt. Pleasant Avenue
West Orange, NJ 07052

JAN 7 2000

Dear Dr. Pituk:

Please refer to your May 7, 1999 new drug application for Cyclessa™ (desogestrel/ethinyl estradiol) Tablets.

We are reviewing the Chemistry section of your submission and have the following comments and information requests. We need your prompt written response to continue our evaluation of your NDA.

1. Please indicate whether there is performed on the incoming batches of drug substance.
2. Please tighten your stability specifications for related substances for individual impurities and for total impurities.
3. Regarding the expiration period, based on the available real time stability data, we recommend a tentative expiration date at 25°C 60% RH.
4. Please revise the stability commitment to include the following statement:
5. Please note that the immediate container should have the following information:
 - a. company name
 - b. expiration date
 - c. a lot number

*If you have any questions, call Jennifer Mercier, B.S., Regulatory Project Manager,
at (301) 827-4260.*

Sincerely,

S - 1/7/2010

Moo-Jhong Rhee, Ph.D.
Team Leader for Division of Reproductive and
Urologic Drug Products (HFD-580)
Division of New Drug Chemistry II
Center for Drug Evaluation and Research

**APPEARS THIS WAY
ON ORIGINAL**

NDA 21-090

Page 3

cc:

Archival ~~_____~~

HFD-580/Div. Files

HFD-580/J.Mercier

HFD-580/Rhee/Boal/Rarick/Allen

HFD-820/DNDC/Gibbs

DISTRICT OFFICE

Drafted by: JM/January 4, 2000

Initialed by: Rumble1.6.00/AlHakim1.7.00/Rhee1.7.00/Rarick1.7.00

final: January 7, 2000

filename: ~~_____~~

INFORMATION REQUEST (IR)

**APPEARS THIS WAY
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Meriue

NDA 21-090

Food and Drug Administration
Rockville MD 20857

MAY 12 1999

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

Dear Mr. Mayo:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: CTR 77 (desogestrel and ethinyl estradiol) Tablets

Therapeutic Classification: Standard (S)

Date of Application: May 7, 1999

Date of Receipt: May 7, 1999

Our Reference Number: 21-090

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on July 6, 1999 in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be March 7, 2000 and the secondary user fee goal date will be May 7, 2000.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). If you have not already fulfilled the requirements of 21 CFR 314.55 (or 601.27), please submit your plans for pediatric drug development within 120 days from the date of this letter unless you believe a waiver is appropriate. Within 120 days of receipt of your pediatric drug development plan, we will notify you of the pediatric studies that are required under section 21 CFR 314.55.

If you believe that this drug qualifies for a waiver of the study of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a

waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" in addition to your plans for pediatric drug development described above. If you do not submit a Proposed Pediatric Study Request within 120 days from the date of this letter, we will presume that you are not interested in obtaining pediatric exclusivity and will notify you of the pediatric studies that are required under section 21 CFR 314.55. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Reproductive and Urologic Drug Products, HFD-580
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, contact Jennifer Mercier, Project Manager, at (301) 827-4260.

Sincerely,


Lana L. Pauls, M.P.H.
Chief, Project Management Staff
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Page 3

cc:

Archival NDA 21-090
HFD-580/Div. Files
HFD-580/J.Mercier
HFD-580/Rarick/Mann/Allen
DISTRICT OFFICE

Drafted by: JM/May 12, 1999

Initialed by:

final:

filename: 21090ACK.WPD

ACKNOWLEDGEMENT (AC)

**APPEARS THIS WAY
ON ORIGINAL**

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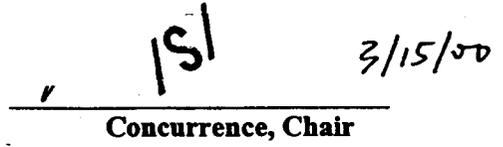
Decisions Made:

- the stability specification will be Q: — @ 30 minutes
- the release specification will be Q: — @ 15 minutes
- A Phase 4 commitment to perform dissolution tests with two timepoints (15 minutes and 30 minutes) for the first three production batches during the stability studies at 40° up to six months and at 25° up to 12 months; after 12-month data is complete, the sponsor should submit that information for the Division to re-evaluate and set the final specification

Action Items:

- Fax meeting minutes to sponsor within 30 days


Minutes Preparer


Concurrence, Chair

**APPEARS THIS WAY
ON ORIGINAL**

cc:

Original NDA

HFD-580/DivFile

HFD-580/Rumble/Mercier

HFD-580/Allen/Rhee/Parekh/Al-Hakim/Madani

drafted: March 9, 2000

concurrence: Rumble3.13.00/Rhee3.14.00/Parekh3.15.00

final: March 15, 2000

MEETING MINUTES

**APPEARS THIS WAY
ON ORIGINAL**

Mercier

Teleconference Minutes

Date: March 2, 2000 **Time:** 11:30 – 12:00 PM **Location:** Parklawn; 17B-43

NDA 21-090 **Drug:** Cylessa (desogestrel/ethinyl estradiol)

Indication: Oral Contraceptive (OC)

Sponsor: Organon, Inc.

Type of Meeting: Guidance (CMC)

Meeting Chair: Moo-Jhong Rhee, Ph.D.

External Lead: Tomas Putik

Meeting Recorder: Jennifer Mercier, B.S.

FDA Attendees:

Moo-Jhong Rhee, Ph.D. – Team Leader, Division of New Drug Chemistry II (DNDCII) @ Division of Reproductive and Urologic Drug Products (DRUDP; HFD-580)

Ali Al-Hakim, Ph.D. – Chemist, DNDCII (HFD-815)

Ameeta Parekh, Ph.D. – Team Leader, Office of Clinical Pharmacology and Biopharmaceutics (OCPB) @ DRUDP (HFD-580)

Soraya Madani, Ph.D. – Biopharmaceutics Reviewer, (OCPB) @ DRUDP (HFD-580)

Jennifer Mercier, B.S. – Regulatory Project Manager, DRUDP (HFD-580)

External Attendees:

Thomas Pituk, Regulatory Affairs, Organon, Inc.

Gertjan Hartholt, Ph.D. – Manufacturing Technology, Organon, Inc. (Oss)

Erma Hoebergen – Manufacturing Technology, Organon, Inc. (Oss)

Stanely Kline, Ph.D. – Analytical Methods Development, Organon, Inc.

Herman Kolman – Regulatory Affairs, Organon, Inc. (Oss)

Henk Koops, Ph.D. – Regulatory Affairs, Organon, Inc. (Oss)

Jay Rheingold, Ph.D. – Product Development, Organon, Inc.

Chris Vermaat, Ph.D. – Quality Assurance, Organon, Inc. (Oss)

Giselle Rose, Regulatory Affairs, Organon, Inc.

Meeting Objective: To discuss the dissolution specifications for Cylessa™ (desogestrel/ethinyl estradiol)

Discussion:

- DRUDP recommends that the dissolution specification for this product be Q — @ 15 min. based on the stability data presented in the NDA
- the purpose of the dissolution specification is to identify problems that may occur with product quality
- this recommendation is consistent with other OC products

Cyclessa (NDA 21-090)

- the Division has proposed an impurities specification for this product that is based on the stability data presented in the NDA
- this recommendation is consistent with other OC products
- the sponsor will provide a response to this recommendation and submit it to the Division by Thursday, February 17, 2000
- the Division will make a decision based upon a reasonable proposal

Dissolution Specification proposed by DRUDP:

- the Division has recommended a Q — 15 minutes for the dissolution specification

Action Items:

- The sponsor will respond to the outstanding issues regarding the dissolution and impurities specifications by Thursday, February 17, 2000
- Fax meeting minutes to sponsor within 30 days


Minutes Preparer

 1/6/00
Concurrence, Chair

APPEARS THIS WAY
ON ORIGINAL

Mercier

Teleconference Minutes

MAR 10 2000

Date: February 23, 2000 **Time:** 11:30 – 12:00 PM **Location:** Parklawn; 17B-45

NDA 21-090 & **Drug:** Cylessa (desogestrel/ethinyl estradiol)

Indication: Oral Contraceptive (OC)

Sponsor: Organon, Inc.

Type of Meeting: Guidance (CMC)

Meeting Chair: Moo-Jhong Rhee, Ph.D.

External Lead: Tomas Putik

Meeting Recorder: Jennifer Mercier, B.S.

FDA Attendees:

Moo-Jhong Rhee, Ph.D. – Team Leader, Division of New Drug Chemistry II (DNDCII) @ Division of Reproductive and Urologic Drug Products (DRUDP; HFD-580)

Soraya Madani, Ph.D. – Biopharmaceutics Reviewer, Office of Clinical Pharmacology and Biopharmaceutics (OCPB) @ DRUDP (HFD-580)

Jennifer Mercier, B.S. – Regulatory Project Manager, DRUDP (HFD-580)

External Attendees:

Thomas Pituk, Regulatory Affairs, Organon, Inc.

Giselle Rose, Regulatory Affairs, Organon, Inc.

Meeting Objective: To discuss the dissolution and impurities specifications for both products.

Decisions made:

Impurities Specification

- the Division has accepted the dissolution specifications for proposed in the original NDA (Q @ 30 min.)

Cylessa (NDA 21-090)

- DRUDP recommends that the dissolution specification for this product be Q @ 15 min. based on the stability data presented in the NDA
- the purpose of the dissolution specification is to identify problems that may occur with product quality
- this recommendation is consistent with other OC products
- the sponsor will provide a response to this recommendation and submit it to the Division by Friday, February 25, 2000
- the Division will then make a determination based upon an acceptable proposal

Action Items:

- The sponsor will respond to the outstanding issues regarding the dissolution and impurities specifications by Friday, February 25, 2000
- Fax meeting minutes to sponsor within 30 days

JS

Minutes Preparer

JS 3/10/00

Concurrence, Chair

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cc:

Original NDA

HFD-580/DivFile

HFD-580/Rumble/Mercier

HFD-580/Allen/Rhee/Boal/Al-Hakim/Madani

drafted: March 2, 2000

concurrence: Rumble3.3.00/Rhee3.6.00/Madani3.6.00

final: March 10, 2000

MEETING MINUTES

APPEARS THIS WAY
ON ORIGINAL

Teleconference Minutes

Date: February 10, 2000 **Time:** 11:00 – 12:00 PM **Location:** Parklawn; 17B-43

NDA 21-090, **Drug:** Cylessa (desogestrel/ethinyl estradiol)

MAR 6 2000

Indication: Oral Contraceptive (OC)

Sponsor: Organon, Inc.

Type of Meeting: Guidance (CMC)

Meeting Chair: Moo-Jhong Rhee, Ph.D.

External Lead: Tomas Putik

Meeting Recorder: Jennifer Mercier, B.S.

FDA Attendees:

Moo-Jhong Rhee, Ph.D. – Team Leader, Division of New Drug Chemistry II (DNDCII) @ Division of Reproductive and Urologic Drug Products (DRUDP; HFD-580)

Jila Boal, Ph.D. – Chemist, DNDCII @ DRUDP (HFD-580)

Ali Al-Hakim, Ph.D. – Chemist, DNDCII

Jennifer Mercier, B.S. – Regulatory Project Manager, DRUDP (HFD-580)

External Attendees:

Organon, Inc.

Thomas Pituk, Regulatory Affairs

Giselle Rose, Regulatory Affairs

Jay Rheingold, Pharmaceutical Development

Organon (Oss)

Herman Kolman, Regulatory

Organon (Ireland)

Dara Clarke, Regulatory

Georgina Keating, QA

Meeting Objective: To discuss the dissolution and impurities specifications for both products.

Decisions made:

Impurities Specification

cc:

Original NDA

HFD-580/DivFile

HFD-580/Rumble/Mercier

HFD-580/Allen/Rhee/Boal/Al-Hakim

drafted: February 23, 2000

concurrence: Rumble2.24.00/Rhee2.25.00/Boal2.25.00

final: March 6, 2000

MEETING MINUTES

**APPEARS THIS WAY
ON ORIGINAL**

Mercier

Teleconference Minutes

Date: January 5, 2000

NDA 21-090. ~~_____~~

Drug: Cyclessa (desogestrel/ethinyl estradiol)
~~_____~~

Indication: Oral Contraceptive

Sponsor: Organon, Inc.

Type of Meeting: Request for Information

FDA Attendees:

Jennifer Mercier, B.S. – Regulatory Project Manager, Division of Reproductive and Urologic Drug Products (DRUDP; HFD-580)

External Attendees:

Giselle Rose, Regulatory Affairs, Organon, Inc.

Meeting Objective: To request the sponsor to submit information for the biopharmaceutics reviewer and Medical Officer.

Decisions made:

- Patient information for CTR 99, Study 092002, Patient #09069
- *In vitro* dissolution data for both NDAs, provide the tables and plots on a CD-ROM. As the plots only represent mean values, regenerate the plots with standard deviation included in the plots (and not % standard deviation or standard error).


Concurrence, Chair

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NDA 21-090
Meeting Minutes
Page 2

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Original NDA
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MEETING MINUTES

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Mercier

Teleconference Minutes

Date: December 20, 1999

NDA 21-090

Drug: Cyclessa (desogestrel/ethinyl estradiol)
(desogestrel/ethinyl estradiol)

Indication: Oral Contraceptive

Sponsor: Organon, Inc.

Type of Meeting: Request for Information

FDA Attendees:

Jennifer Mercier, B.S. – Regulatory Project Manager, Division of Reproductive and Urologic Drug Products (DRUDP; HFD-580)

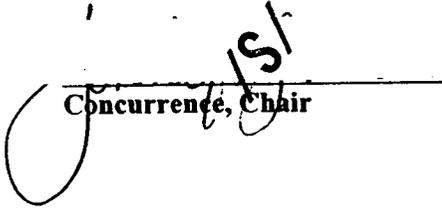
External Attendees:

Giselle Rose, Regulatory Affairs, Organon, Inc.

Meeting Objective: To request information for the biopharmaceutics reviewer.

Decisions made:

- Request the sponsor to submit the summary tables for the analytical assay methods in the Human Pharmacokinetics and Bioavailability studies submitted to NDAs 21-090


Concurrence, Chair

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NDA 21-090

Meeting Minutes

Page 2

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Original NDA

HFD-580/DivFile

HFD-580/Rumble/Mercier

MEETING MINUTES

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Mercier

Teleconference Minutes

Date: November 30, 1999 and December 7, 1999

NDA 21-090. _____

Drug: Cyclessa (desogestrel/ethinyl estradiol)

Indication: Oral Contraceptive

Sponsor: Organon, Inc.

Type of Meeting: Request for Information

FDA Attendees:

Jennifer Mercier, B.S. – Regulatory Project Manager, Division of Reproductive and Urologic Drug Products (DRUDP; HFD-580)

External Attendees:

Giselle Rose, Regulatory Affairs, Organon, Inc.

Meeting Objective: To request information for the biopharmaceutics reviewer.

Decisions made:

- Request the sponsor to submit responses to the following information:
 - In NDA 21-090, Vol. 17, Study 092004, Page 0059, Tables and 6, SHGB and testosterone measurements were presented as Mean \pm SEM. However, it is not clear what the mean represents. This applies to _____ as well.
 - IN NDA 21-090, Vol. 17, Study 092004, Pages 0045 – 0046, there is a description (in statistical and Analytical Methods Section of the report) of serum concentration plots. However, plots were not provided (in the Results Section). This applies to _____ as well.
 - In NDA 21-090, Vol. 16, Page 0027, Table 7, explain why the half-life for EE in multiple dose study was almost twice that of the single dose studies.
 - FDA form 483 for site 12 (Dr. Fordyce)

JS

Concurrence, Chair

NDA 21-090

Meeting Minutes

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MEETING MINUTES

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Mercier

Teleconference Minutes

Date: November 19, 1999

NDA 21-090

Drug: Cyclessa (desogestrel/ethinyl estradiol)

Indication: Oral Contraceptive

Sponsor: Organon, Inc.

Type of Meeting: Request for Information

FDA Attendees:

Jennifer Mercier, B.S. – Regulatory Project Manager, Division of Reproductive and Urologic Drug Products (DRUDP; HFD-580)

External Attendees:

Giselle Rose, Regulatory Affairs, Organon, Inc.

Meeting Objective: To clarify the requirements for a safety update.

Decisions made:

- There are no ongoing trials for these two products and the sponsor will cross-reference NDA 20-713 and NDA 20-071 for safety information.


Concurrence Chair

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Meeting Minutes
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MEETING MINUTES

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Mercier

Teleconference Minutes

Date: November 8 and December 2, 1999

NDA 21-090, —

Drug: Cyclessa (desogestrel/ethinyl estradiol)

Indication: Oral Contraceptive

Sponsor: Organon, Inc.

Type of Meeting: Request for Information

FDA Attendees:

Jennifer Mercier, B.S. – Regulatory Project Manager, Division of Reproductive and Urologic Drug Products (DRUDP; HFD-580)

External Attendees:

Giselle Rose, Regulatory Affairs, Organon, Inc.

Meeting Objective: To request information for the Medical Officer.

Decisions made:

- Request the sponsor to submit copies of all available medical records on the following patients who had vascular adverse events (including hospital admission history, physical, and discharge summaries):
 - CTR 77, Study 092-002, Patient #20029
 - CTR 99, Study 092-001, Patient #09035
 - CTR 99, Study 092-002, Patient #09069
 - CTR 99, Study 092-002, Patient #49052


Concurrence Chair

cc:
Original NDA
HFD-580/DivFile
HFD-580/Rumble/Mercier

MEETING MINUTES

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3 pages

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Mercier

Teleconference Minutes

Date: October 22 and 26, 1999

NDA 21-090

Drug: Cyclessa (desogestrel/ethinyl estradiol)

Indication: Oral Contraceptive

Sponsor: Organon, Inc.

Type of Meeting: Request for Information

FDA Attendees:

Jennifer Mercier, B.S. – Regulatory Project Manager, Division of Reproductive and Urologic Drug Products (DRUDP; HFD-580)

External Attendees:

Giselle Rose, Regulatory Affairs, Organon, Inc.

Meeting Objective: To request information for the biopharmaceutics reviewer.

Decisions made:

- Request the sponsor to submit the labeling in WORD format
- Report synopsis, tables, and graphs for CTR 77 PK studies 092004, 092005, and 092006; CTR 99 PK studies 092003, 013007, and 013008, in WORD format.

JST
Concurrence Chair

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NDA 21-090
Meeting Minutes
Page 2

cc:
Original NDA
HFD-580/DivFile
HFD-580/Rumble/Mercier

MEETING MINUTES

**APPEARS THIS WAY
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Mercier

Teleconference Minutes

Date: June 25, 1999

NDA 21-090

Drug: Cyclessa (desogestrel/ethinyl estradiol)

Indication: Oral Contraceptive

Sponsor: Organon, Inc.

Type of Meeting: Request for Information

FDA Attendees:

Jennifer Mercier, B.S. -- Regulatory Project Manager, Division of Reproductive and Urologic Drug Products (DRUDP; HFD-580)

External Attendees:

Giselle Rose, Regulatory Affairs, Organon, Inc.

Meeting Objective: To request information for the biopharmaceutics reviewer.

Decisions made:

- Request the sponsor to submit the publications regarding the metabolism of desogestrel referenced in the Annotated Labeling.


Jennifer Mercier, Chair

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NDA 21-090

Meeting Minutes

Page 2

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Original NDA

HFD-580/DivFile

HFD-580/Rumble/Mercier

MEETING MINUTES

**APPEARS THIS WAY
ON ORIGINAL**

Meeting Minutes

Date: June 15, 1999 **Time:** 8:00-8:30 AM

Location: Parklawn; 17B-43

NDA 21-090

Drug: CTR-77 (Desogestrel/Ethinyl Estradiol) **Indication:** OC

Sponsor: Organon, Inc.

Type of Meeting: Filing Meeting

Meeting Chair: Lisa Rarick, M.D.

Meeting Recorder: Jennifer Mercier

FDA Attendees:

Lisa Rarick, M.D. – Director, Division of Reproductive and Urologic Drug Products;

(DRUDP; HFD-580)

Daniel Davis, M.D. – Medical Officer, DRUDP (HFD-580)

Brenda Gierhart, M.D. – Medical Officer, DRUDP (HFD-580)

David Lin, Ph.D. – Chemist, Division of New Drug Chemistry II (DNDCII) @ DRUDP (HFD-580)

Jila Boal, Ph.D. – Chemist, DNDCII @ DRUDP (HFD-580)

Ameeta Parekh, Ph.D. – Team Leader, Office of Clinical Pharmacology and Biopharmaceutics

(OCPB) @ DRUDP (HFD-580)

Soraya Madani, Ph.D. – Biopharmaceutics Reviewer, OCPB @ DRUDP (HFD-580)

Meeting Objective: To determine if the submitted application is fileable.

Decisions made:

Clinical

- this application is fileable
- clinical study sites have been identified

Pharmacology

- review is complete, recommend approval

Chemistry

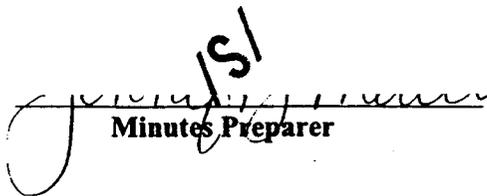
- this application is fileable

Biopharmaceutics

- this application is fileable

Unresolved decisions: None

Action Items: None


Minutes Preparer


Concurrence, Chair

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Original NDA

HFD-580/DivFile

HFD-580/Rumble/Mercier

HFD-580/Rarick/Mann/Davis/Gierhart/Madani/Parekh/Lin/Boal/Rhee/Kammerman

drafted: June 15, 1999

concurrence: Moore6.21.99Rarick6.21.99/Mann/Davis6.23.99/Gierhart6.22.99/Madani6.23.99/
Parekh6.21.99/Lin6.21.99/Boal6.25.99/Rhee/Kammerman

final: June 25, 1999

MEETING MINUTES

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ON ORIGINAL

NDA 21-090

Cyclessa
(desogestrel/ethinyl estradiol) Tablets

Organon, Inc.

3S

Project Manager: Jennifer Mercier
Phone: 7-4260

Resubmission Date: October 20, 2000
User Fee Goal Date: December 20, 2000

Advisory Committee
N/A

NDA 21-090

Cyclessa
(desogestrel/ethinyl estradiol) Tablets

Organon, Inc.

3S

Project Manager: Jennifer Mercier
Phone: 7-4260

Resubmission Date: October 20, 2000
User Fee Goal Date: December 20, 2000

Federal Register Notice
N/A

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