CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-653/S-022 & 19-697/S-018

Trade Name: Ortho-Cyclen 0.25mg/0.035mg

Ortho Tri-Cyclen 0.18mg/0.035mg, 0.215mg/0.035mg, 0.25mg/0.035mg

Generic Name: norgestimate/ethinyl estradiol tablets

Sponsor: Johnson RW

Approval Date: 11/22/1999

Indications: Ortho-Cyclen & Ortho Tri-Cyclen: For the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

Ortho Tri-Cyclen: For the treatment of moderate acne vulgaris in females, greater than or equal to 15 years of age, who have no known contradictions to oral contraceptive therapy, desire contraception, have achieved menarche and are unresponsive to topical anti-acne medications.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-653/S-022 & 19-697/S-018

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APPLICATION NUMBER:

19-653/S-022 & 19-697/S-018

APPROVAL LETTER

NDA 19-653/S-022
NDA 19-697/S-018

The R.W. Johnson Pharmaceutical Research Institute
Attention: William Sisco
Associate Director, Regulatory Affairs
920 Route 202 South
P. O. Box 300
Raritan, NJ 08869-0602

NOV 22 1999

Dear Mr. Sisco:

Please refer to your supplemental new drug applications dated April 8, 1999, received April 9, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ORTHO-CYCLEN® (norgestimate/ethinyl estradiol) Tablets and ORTHO TRI-CYCLEN® (norgestimate/ethinyl estradiol) Tablets.

We note that these supplements were submitted as 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

These supplemental new drug applications provide for a combination **Brief Summary Patient Package Insert** and **Detailed Patient Labeling** to replace the two separate pieces, **Detailed Patient Labeling** and **Brief Summary**, as per the Agency's final rule dated May 25, 1989, regarding Oral Contraceptives; Patient Package Insert Requirements. Your submission stated April 9, 1999, as the implementation date for the changes.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (patient package insert submitted April 8, 1999). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, contact Jennifer Mercier, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

11/22/99

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cc:
Archival NDAs 19-653, 19-697
HFD-580/Div. Files
HFD-580/Jbest/JMercier
HFD-580/Rarick/Mann/Allen/Bennett/Rumble
HF-2/MedWatch (with labeling)
HFD-002/ORM (with labeling)
HFD-103/ADRA (with labeling)
HFD-40/DDMAC (with labeling)
HFI-20/Press Office (with labeling)
HFD-400/OPDRA (with labeling)
HFD-613/OGD (with labeling)
HFD-21/ACS (with labeling) - for drug discussed at advisory committee meeting.
HFD-095/DDMS-IMT (with labeling)
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: JAB/November 18, 1999
Initialed by:Rumble/Mann/Rarick
final:JAB/November 22, 1999
filename: N19653696SLRsAPL1199.doc

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-653/S-022 & 19-697/S-018

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ORIGINAL

NDA NO. 19697 REF. NO. 22-018

NDA SUPPL FOR CBE

THE R.W. JOHNSON
PHARMACEUTICAL RESEARCH INSTITUTE
ROUTE 202, P.O. BOX 300, RARITAN, NEW JERSEY 08869-0602

APR 0 8 1999

Lisa Rarick, M.D.
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation II, HFD-580
Attn: Document Control Room
5600 Fishers Lane
Rockville, MD 20857-1706

NDA 19-653
ORTHO-CYCLEN® Tablets
(norgestimate/ethinyl estradiol)

Please Cross refer to:

NDA 19-697
ORTHO TRI-CYCLEN® Tablets
(norgestimate/ethinyl estradiol)

CHANGES BEING EFFECTED IN 30 DAYS

Dear Dr. Rarick:

Reference is made to our approved New Drug Applications 19-653 and 19-697 for ORTHO-CYCLEN® and ORTHO TRI-CYCLEN® respectively, and to the Agency's final rule dated May 25, 1989 regarding Oral Contraceptives; Patient Package Insert Requirements. (Federal Register 54 FR 100, Docket No. 86N-0337). This final rule eliminated the requirement for a physically separate summary, but would require a summary to be included as a part of the patient package insert.

At this time, we are submitting a Changes Being Effected Supplement which includes final printed labeling for a combination Brief Summary Patient Package Insert and Detailed Patient Labeling for ORTHO-CYCLEN® and ORTHO TRI-CYCLEN® Tablets. This component will replace the two separate pieces, Detailed Patient Labeling and Brief Summary, which are now included in the overwrap for these two products. There were no textual changes made to either the Brief Summary or the Detailed Patient Labeling. We plan to implement this change in thirty (30) days from the date of this letter.

0,1C
RLS
4/13/99

We are submitting 20 copies (10 on heavy-weight paper) of the Final Printed Labeling of the Combination Brief Summary/Detailed Patient Labeling (component code # 640-50-900-1).

I agree 11/20/99

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If you have any questions, please do not hesitate to contact me directly at (908) 704-4301, or at (908) 704-4600, our number designated only for FDA use.

Sincerely,

The R. W. Johnson
Pharmaceutical Research Institute

William R. Sisco
Associate Director
Regulatory Affairs

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-697/S-018

APR 12 1999

The R. W. Johnson Pharmaceutical Research Institute
920 Route 202 South
P. O. Box 300
Raritan, New Jersey 08869-0602

Attention: William R. Sisco
Associate Director, Regulatory Affairs

Dear Mr. Sisco:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: ORTHO TRI-CYCLEN®

NDA Number: 19-697

Supplement Number: S-018

Date of Supplement: April 8, 1999

Date of Receipt: April 9, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on Jun 8, 1999 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 Reproductive and Urologic Drug Products, HFD-580
Office of Drug Evaluation II
Attention: Document Control Room 17B-20
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Terri F. Rumble
Chief, Project Management Staff
Division of Reproductive and Urologic
Drug Products, HFD-580
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 19-697/S-018
HFD-580/Div. Files
HFD-580/CSO/KISH

SUPPLEMENT ACKNOWLEDGEMENT