

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-490

PHARMACOLOGY REVIEW(S)

PHARMACOLOGY/TOXICOLOGY COVER SHEET

NDA number: 21-490

Review number: 1

Sequence number/date/type of submission: Original NDA

Information to sponsor: Yes () No (X)

Sponsor and/or agent: Warner Chilcott, Inc.

Manufacturer for drug substance : —

Reviewer name: Alex Jordan

Division name: DRUDP

HFD #: 580

Review completion date: 1/7/03

Drug:

Trade name: Ovcon 35 —

Generic name (list alphabetically): ethinyl estradiol and norethindrone

Code name:

Chemical name:

CAS registry number:

Mole file number:

Molecular formula/molecular weight:

Structure:

Relevant INDs/NDAs/DMFs: NDA 17-761

Drug class: estrogen/progestin

Indication: contraception

Clinical formulation: norethindrone, ethinyl estradiol, sucralose, spearmint flavor, maltodextrin, povidone, sodium starch glycolate, corn starch, magnesium stearate, dibasic calcium phosphate, lactose.

Route of administration: oral

Proposed use: contraception

Disclaimer: Tabular and graphical information is from sponsor's submission unless stated otherwise.

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Alexander W. Jordan
1/23/03 11:10:03 AM
PHARMACOLOGIST