

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-864

**RISK ASSESSMENT and RISK MITIGATION
REVIEW(S)**

MEMORANDUM

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

DATE: November 21, 2005

TO: Daniel Shames, MD, Director
Division of Reproductive and Urologic Drug Products
HFD-580

VIA: John Kim, RPh, JD, Project Manager
Division of Reproductive and Urologic Drug Products
HFD-580

FROM: Catherine Miller, MT(ASCP)
Patient Product Information Specialist
Division of Surveillance, Research, and Communication Support
HFD-410

THROUGH: Gerald Dal Pan, MD, MHS, Director
Division of Surveillance, Research, and Communication Support
HFD-410

SUBJECT: DSRCs Review of Patient Labeling for Levonorgestrel (LNG) (90 µg)/Ethinyl Estradiol (EE) (20µg) Continuous Use, NDA 21-864

Background:

The sponsor submitted Detailed Patient Labeling for Levonorgestrel (LNG) (90 µg)/Ethinyl Estradiol (EE) (20µg) Continuous Use, NDA 21-864, on May 27, 2005, for the prevention of pregnancy in women who elect to use this product as a method of contraception.

Comments and recommendations:

We have the following comments and recommendations:

1. Revise the patient labeling to follow the March 2004, Draft Guidance; *Guidance for Industry: Labeling for Combined Oral Contraceptives*. This patient labeling does not follow the draft guidance, contrary to the sponsor's statement in their cover letter.
2. Avoid the use of UPPER CASE and *italic* lettering to emphasize important information. Upper case and italic lettering is difficult to read. Emphasize a word or statement by bolding or increasing the font size. The brand name is the exception to this recommendation and may be in upper case letters.

3. Lower the reading level. The submitted patient labeling has a Flesch-Kincaid reading level of 10.7 (approximately an eleventh grade reading level) and a Flesch reading ease of 49%. Optimally, all patient information should be written at a 6th to 8th grade reading level and have a reading ease of at least 60% (60% corresponds to an 8th grade reading level) to enhance understanding by patients with lower literacy.

Please call us if you have any questions.

**Appears This Way
On Original**

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

/s/

Catherine Miller
11/21/2005 10:21:24 AM
DRUG SAFETY OFFICE REVIEWER

Toni Piazza Hepp
11/22/2005 01:11:02 PM
DRUG SAFETY OFFICE REVIEWER
for Gerald Dal Pan