

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75256_S1

APPROVAL LETTER

ANDA 75-256/S-001

Duramed Pharmaceuticals, Inc.
Attention: John R. Rapoza, M.S., R.Ph.
5040 Lester Road
Cincinnati, OH 45213

OCT 28 1999

Dear Sir:

This is in reference to your supplemental new drug application dated August 31, 1999, submitted pursuant to 21 CFR 314.70 regarding your abbreviated new drug application for Apri™ (desogestrel and ethinyl estradiol) Tablets, 0.15 mg and 0.03 mg, respectively, (21- and 28-day cycles).

The supplemental application provides for revised carton, container, and insert labeling reflecting the addition of the proprietary name "Apri".

We have completed the review of this supplemental application and it is approved. However, at the time of next printing, further revise your insert labeling as follows:

1. PHYSICIAN INSERT:

a. CLINICAL PHARMACOLOGY

First paragraph, last sentence: Revise "increase" to read "increases".

b. WARNINGS

i. "1. THROMBOEMBOLIC DISORDERS...Myocardial infarction", third paragraph, third sentence: Revise "... (see section 9 in Warnings)." to read "... (see section 9 in WARNINGS)."

ii. "TABLE III:" Revise to read "* Deaths are birth-related" and "** Deaths are method-related" [Note: Insert a hyphen].

iii. "9. ELÉVATED BLOOD PRESSURE", third paragraph, second sentence: "...oral contraceptives should be discontinued." [Note: Add an "s" to "contraceptive"].

c. PRECAUTIONS

"8. INTERACTIONS WITH LABORATORY TESTS":

i. "d.": Revise to read "Sex hormone..." [Note: Delete the hyphen].

ii. "e.": Revise to read "...may be decreased or unchanged."

d. REFERENCES

i. #25: Revise "...Biosocial Sci..." to read "...J Biosocial Sci..."

ii. #79: Revise "...contraceptives. 1988..." to read
"...contraceptives. JAMA 1988..."

iii. #100: Revise to read "...Health of Young Women..."

e. DETAILED PATIENT LABELING:

i. "ANNUAL NUMBER OF BIRTH-RELATED OR METHOD-RELATED DEATHS..." Table: Revise to read "* Deaths are birth-related" and "*** Deaths are method-related" [Note: Insert a hyphen].

ii. "HOW TO TAKE THE PILL..." section:

A. First sentence: Revise "BEFORE YOU START TAKING YOUR PILLS:" to read "BEFORE YOU START TAKING YOUR PILLS:"

B. "2. LOOK AT YOUR PILL PACK...", second paragraph: Insert quotation marks around the word "reminder".

C. "4. BE SURE YOU HAVE READY...": Insert the word "method" after the word "back-up".

iii. "WHAT TO DO IF YOU MISS PILLS:" section:

A. "If you MISS 1...", Item 1., third sentence: Revise to read "...you may take 2 pills in 1 day."

B. "If you MISS 2...in THE 3RD WEEK:": Revise to read
"...THE 3RD WEEK:"

iv. "A REMINDER FOR THOSE ON 28 DAY PACKS:": Revise to read
"28-DAY" [Note: Insert a hyphen].

2. DETAILED PATIENT LABELING INSERT:

See Comments (1)(e)(i), (1)(e)(ii)(B & C), and (1)(e)(iii & iv) under PHYSICIAN INSERT.

3. BRIEF SUMMARY PATIENT PACKAGE INSERT (21-DAY):

See Comments (1)(e)(ii)(C) and (1)(e)(iii)(A) under PHYSICIAN INSERT.

4. BRIEF SUMMARY PATIENT PACKAGE INSERT (28-DAY):

See Comments (1)(e)(ii)(B & C) and (1)(e)(iii)(A) under PHYSICIAN INSERT.

Revised labels and labeling may be submitted in an annual report provided the changes are described in full. We refer you to 21 CFR 314.81(b)(2)(iii) for guidance.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

/s/
Robert L. West, M.S., R.Ph.
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

for 10-28-1999