CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75256_S4

APPROVAL LETTER

ANDA 75-256/S-004

JUL 11 2001

Duramed Pharmaceuticals, Inc.
Attention: John R. Rapoza
5040 Duramed Drive
Cincinnati, OH 45213

Dear Sir:

This is in reference to your supplemental new drug application dated February 23, 2001, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg.

The supplemental application submitted as "Prior Approval Supplement" provides for a new regulatory analytical method for placebo tablets.

We have completed the review of this supplemental application, and it is approved.

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/

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research