CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75256_S5

APPROVAL LETTER

ANDA 75-256/S-005

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

JUL 27

Dear Sir:

This is in reference to your supplemental new drug application dated March 19, 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 "Supplement - Changes Being Effected in 30 Days" provides for an alternate manufacturing site for the drug substance manufacturer -

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/ 7-26-01

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