CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75256_S2

APPROVAL LETTER

ANDA 75-256/S-002

JUN 28 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 December 8, 2000, 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.

Reference is also made to your amendments dated May 30, and June 21, 2001.

The supplemental application submitted as "Supplement - Changes Being Effected in 30 Days" provides for a new regulatory analytical method for dissolution testing.

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.

Validation of the regulatory method has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies, which may be identified.

The material submitted is being retained in our files.

Sincerely yours,

/S/ for 6-27-01

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