# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**75256_S4**

# CORRESPONDENCE

DURAmed

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**Duramed Pharmaceuticals, Inc.**
5040 Duramed Drive
Cincinnati, Ohio 45213
(513) 731-9900

# PRIOR APPROVAL SUPPLEMENT

February 23, 2001

Mr. Gary Buehler
Acting Director, Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

NDA NO. 75-256 REF NO. SCS-004
NDA SUPPL FOR CONTROL REV.

**RE:** **ANDA #75-256 Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg**
**Subject:** **New Regulatory Method for Placebo Identification**

Dear Mr. Buehler:

Duramed Pharmaceuticals, Inc., hereby submits a prior approval supplement to ANDA 75-256 for Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg in accordance with the guidance for industry titled, "Changes to an Approved NDA or ANDA" dated November 1999. In this supplement, we provide for a new regulatory analytical test method for placebo tablet identification.

This supplement is submitted in one (1) volume, and includes two (2) copies, an archival copy and a review copy. Because this is a non-USP drug product, two additional copies of the method validation are provided in red folders.

We certify that a true copy of the supplement as described in 21 CFR 314.94 (d)(5) has been provided to the Food and Drug Administration, Cincinnati, District Office in Cincinnati, Ohio.

Please direct any written communications to me at the above address. If you have any questions or require any additional information, please contact Ms. Angie Stewart at 513 731-9900, by fax at 513 458-6007, or the undersigned at 513 458-7274.

Sincerely,

John R. Rapoza, M.S., R.Ph.
Sr. Vice President, Regulatory Affairs