

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75256_S6

CORRESPONDENCE

PRIOR APPROVAL SUPPLEMENT

March 21, 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 20855-2773NDA NO. 75-256 REF NO. SCR-006
NDA NO. FOR MANUFACTURE Rev.**RE: ANDA #75-256 Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg**
Subject: Request to Release Batch

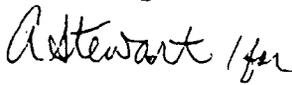
Dear Mr. Buehler:

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 this supplement, we request an exemption to release one batch.

This supplement is submitted in one (1) volume, and includes two (2) copies, an archival copy and a review copy. 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