CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75256_S3

CORRESPONDENCE

ANDA 75-256/S-003

14 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 January 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 "Prior Approval Supplement" provides for

The supplemental application is deficient and, therefore, not approvable under Section 505 of the Act for the following reasons:

1. Please clarify your continued compliance to 21 CFR 211.110(a)(3) upon

2. Please submit the nd finished product release data for all 47 batches cited in your submission.

The file on this supplemental application is now closed. You are required to take an action described under 21 CFR 314.120 which will either amend or withdraw the supplemental application. Your amendment should respond to all the deficiencies listed. A partial reply will not be considered for review, nor will the review clock will be reactivated until all the deficiencies have been addressed. The response to this letter will be considered a MINOR amendment and should be so designated in your cover letter.

If you have substantial disagreement with our reasons for not approving the supplemental application, you may request an opportunity for a hearing.

Sincerely yours,

(/S/) for 6/14/01

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

DURAmed

The Art of Leadership...
The Science of Change

Duramed Pharmaceuticals, Inc.
5040 Duramed Drive
Cincinnati, Ohio 45213

(513) 731-9900
(800) 543-8338

October 23, 2001

SCS-003/PA.

Mr. Gary Buehler
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

RE: **ANDA 75-256: Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg**

Subject: MINOR AMENDMENT TO PRIOR APPROVAL SUPPLEMENT S-003

Dear Mr. Buehler:

Reference is made to a letter dated 6/14/01 concerning minor deficiencies in our supplement S-003 to abbreviated new drug application (ANDA) 75-256 for Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg for Specifically, the letter requested that Duramed clarify its continued compliance with 21 CFR 211.110 (a) (3) upon

finished product data for all of the batches cited in the submission. We now amend the supplement by supplying the requested data and proposing

This supplement is submitted in one (1) volume and includes two (2) copies, an archival (blue) copy and a review (red) copy. We certify that a true copy of this supplement in accordance with 21 CFR 314.70 (a), has been provided to the Food and Drug Administration, Cincinnati, District Office in Cincinnati, Ohio.

Please direct any written communications regarding this ANDA 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

CENTER FOR DRUG
OCT 25 2001

Enclosures:
Completed Form FDA 356h

DURAmed

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The Science of Change

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

January 19, 2001

NDA NO. 75-256 REF NO. SCS-003
NDA SUPPL FOR CONTROL REVISION

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

RE: **ANDA 75-256: Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg**

Subject: **PRIOR APPROVAL SUPPLEMENT**
Deletion of an In-Process Control Specification

Dear Mr. Buehler:

Duramed Pharmaceuticals, Inc. (Duramed) submits today, in accordance with 21 CFR 314.70 (b) (2) (iv), a prior approval supplement to abbreviated new drug application (ANDA) 75-256 for Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg seeking approval to . Specifically, we are providing data for the last 20 consecutive batches with values of 97.0% of label claim for Desogestrel and 98.0% of label claim for Ethinyl Estradiol, and average tablet content uniformity values of 98.6% of label claim for Desogestrel and 100.4% of label claim for Ethinyl Estradiol. **Given these data, we request that the**

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Please direct any written communications regarding this ANDA 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,

On behalf of

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

Enclosures:
Completed Form FDA 356h