CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75256_S2

CORRESPONDENCE

DURAmed

The Art of Leadership...
The Science of Change

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

June 21, 2001

TELEPHONE AMENDMENT

NEW CORRESP
NC

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 / S-002 Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg
Subject: METHODS VALIDATION COMMITMENT LETTER

Dear Mr. Buehler:

Reference is made to a telephone call on June 21, 2001 from Ms. Michelle Dillahunt concerning our supplement to the referenced ANDA drug product in which we requested to change our dissolution method. Ms. Dillahunt stated that the chemistry review is complete; however, the methods validation is still pending. She requested a letter of commitment to work with the FDA to resolve any issues regarding methods validation.

Duramed commits to resolving any issues discovered by the FDA's Field Philadelphia Laboratory as part of their method validation study on Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg.

This amendment is submitted in one (1) volume, and includes two (2) copies, an archival copy and a review copy. In addition, a copy was faxed to Ms. Michelle Dillahunt at 301-594-0180.

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

Please direct any written communications regarding this ANDA to the undersigned at the above address. If you have any questions or require any additional information, please contact Ms. Annette Arlinghaus at (513) 731-9900, by fax at (513) 458-6007, or the undersigned at (513) 458-7274.

Sincerely,

A. Arlinghaus /for

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

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JUN 2 2 2001
OGD
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The Art of Leadership...
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Duramed Pharmaceuticals, Inc.
5040 Duramed Drive
Cincinnati, Ohio 45213
(513) 731-9900

May 30, 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

NEW CORRESP

RE: **ANDA #75-256/S-002 Desogestrel and Ethinyl Estradiol Tablets, 0.15 mg/0.03 mg**
Subject: **Analytical Methods Validation**

Dear Mr. Buehler:

Reference is made to an ANDA Method Validation Letter dated May 21, 2001 in which samples were requested in order to perform methods validation studies for a supplement filed to ANDA 75-256 Desogestrel and Ethinyl Estradiol Tablets. In this supplement, we submitted an improved regulatory analytical dissolution test method.

Samples were sent to Mr. Wayne Smith at the FDA laboratory in Philadelphia. Please note that the bioequivalence batch is expired. A batch not in the ANDA is substituted for methods validation. This submission is an unsolicited amendment to the ANDA providing a copy of the batch record and a certificate of analysis for the batch of tablets sent to the Philadelphia lab for methods validation.

Please direct any written communication regarding this submission to the undersigned at the above address or by FAX at 513-731-5270. If you have any questions or require additional information, please contact the same at 513-731-9900.

CENTER FOR DRUG EVALUATION AND RESEARCH
JUN 01 2001

Sincerely,

Annette Arlinghaus

Annette Arlinghaus
Associate Director, Regulatory Submissions

DURAmed

The Art of Leadership...
The Science of Change

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

SUPPLEMENT CHANGES BEING EFFECTED IN 30 DAYS

December 8, 2000

NDA NO. [redacted] REF N[redacted]
NDA SUPPL FOR [redacted]

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: **CBE Supplement 30 Day for an Improved Regulatory Method for Dissolution**

Dear Mr. Buehler:

Duramed Pharmaceuticals, Inc., hereby submits a Changes Being Effected 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 an improved regulatory analytical dissolution test method.

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. Annette Arlinghaus at 513 731-9900, by fax at 513 458-6007, or the undersigned at 513 458-7274.

Sincerely,

Annette Arlinghaus / for

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