CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75256_S1

CORRESPONDENCE

DURAmed

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The Science of Change

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

August 31, 1999

PRIOR APPROVAL LABELING SUPPLEMENT

NDA NO. 75256 REF NO. SL-001
NDA SUPPL FOR Labeling Revision
AX

Mr. Douglas L. Sporn
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: Pre-Approval Supplement: **EXPEDITED REVIEW REQUESTED.**
Inclusion of brand name **Apri** in approved product labeling.

Dear Mr. Sporn:

Reference is made to a telephone conversation between Mr. Robert West, Director, Division of Labeling Review and Program Support, and Mr. John Rapoza of Duramed on August 26, 1999. In this conversation, Messrs. West and Rapoza discussed the appropriate mechanism for Duramed to submit to FDA labeling for the above referenced product, employing the brand name **Apri**.

It was agreed that a Pre-Approval Supplement would be filed. Therefore, as required by 21 CFR 314.70 (b)(3), Duramed submits the Pre-Approval Supplement containing final draft cartons, blister cards and sachets for the 21 and 28 count dosing regimens for Desogestrel and Ethinyl Estradiol Tablets, as well as final printed labeling for the Physician Insert, Detailed Patient Insert and Brief Patient Inserts. The labeling differs from the approved labeling only in 1) includes use of the brand name **Apri** and 2) graphic/color changes. Side-by-side labeling comparisons are included in this supplement, comparing the revised labeling to the approved labeling.

It should be noted that just the brand name **Apri** has already been submitted (with five others) via an earlier supplement (see copy of cover letter, attached) in order to place the name in the queue for review by the nomenclature committee. This supplement provides labeling copy for a concurrent review by the Labeling Review Division. Via this current supplement, Duramed now requests that only **Apri** and **Enpresse** be forwarded to the nomenclature committee. The remaining four names are hereby withdrawn.

Also, under 21 CFR 314.70 (b), Duramed requests **expedited review** of this supplement. A delay in making the change described above would prevent Duramed from launching this product, thus imposing an extraordinary hardship.

Duramed has not been delinquent in seeking a name for this product. Since filing this ANDA in November of 1997, Duramed has proposed six names for the product. All but one has been rejected by the nomenclature committee. The one exception (Ovatrel) has been recently classified by our attorneys as unacceptable from a trademark perspective, because of possible infringement. In addition, during the prosecution of this ANDA, Duramed, on numerous occasions, sought advice from FDA officials on how to distinguish an acceptable name from an non-acceptable name. For whatever reason, this advice was not forthcoming. Hence, Duramed arrived at the approved stage for the application without a name. This absence of a brand name places Duramed at an

extreme disadvantage in the marketing of this drug product. An oral contraceptive, from a marketing perspective, requires a brand name to have a chance of being accepted by patients utilizing a generic contraceptive product.

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 technical section as described in 21 CFR 314.50 (d)(5) has been provided to the Food and Drug Administration, Cincinnati, District Office in Cincinnati, Ohio.

Please direct any communication regarding this supplement to me at the above address. If you have questions or require any additional information, please contact Mr. William Stoltman 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.
Vice President, Regulatory and Quality Affairs

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

CHANGES BEING EFFECTED LABEL SUPPLEMENT

October 22, 1999

NEW CORRESP

NC

Mr. Douglas L. Sporn
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: Changes Being Effected Supplement:
Use of brand name *Apri™* in approved product labeling.

Dear Mr. Sporn:

Reference is made to a Supplement to this application dated August 31, 1999. This supplement provided for the addition of the Brand name **Apri™** to finished product labeling in which the proposed name was inserted into the approved labeling. Reference is also made to conversations between Mr. Robert West, Director, Division of Labeling Review and Program Support and Mr. John Grace, Team Leader for the Division of Labeling Review and Program Support and Mr. John Rapoza of Duramed on October 18, 1999. In these conversations, Messrs. West and Grace discussed the status of the referenced submission. The substance of these discussions was that the brand name, "Apri" was reviewed and approved by the Division. Based on the verbal approval status of the brand name, and the fact that the use of **Apri™** will enhance the acceptance and correct use of this product, Duramed now submits this Special Labeling Supplement – Changes Being Effected for the labeling revision inserting the trade name "Apri" in the approved product labeling.

Use of the brand name "Apri" in the labeling for marketed product will begin October 22, 1999. This C.B.E. supplement is submitted in two (2) copies, an archival copy and a review copy with with cross reference to the supplement dated August 31, 1999.

We certify that a true copy of the technical section as described in 21 CFR 314.50 (d)(5) has been provided to the Food and Drug Administration, Cincinnati, District Office in Cincinnati, Ohio.

Please direct any communication regarding this supplement to me at the above address. If you have questions or require any additional information, please contact Mr. William Stoltman at 513/731-9900, by fax at 513/458-6007 or the undersigned at 513/458-7274.

Sincerely,

For

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

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

November 1, 1999

NEW CORRESP
NC
11/5/1999

Mr. Douglas L. Sporn
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: Withdrawal of Changes Being Effected Supplement:

Dear Mr. Sporn:

Reference is made to a Pre-Approval Supplement to this application filed August 31, 1999, as well as the approval letter for this supplement faxed to Duramed Pharmaceuticals on November 1, 1999. Reference is also made to a Changes Being Effected Supplement filed to this application dated October 22, 1999.
At this time, Duramed withdraws the Changes Being Effected Supplement. This supplement is submitted in one volume and includes two (2) copies, one archival copy and a review copy.
We certify that a true copy of the technical section as described in 21 CFR 314.50 (d)(5) has been provided to the Food and Drug Administration, Cincinnati, District Office in Cincinnati, Ohio.

Please direct any communication regarding this supplement to me at the above address. If you have questions or require any additional information, please contact Mr. William Stoltman at 513/731-9900, by fax at 513/458-6007 or the undersigned at 513/458-7274.

Sincerely,

for

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