DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-443/S-005

Duramed Pharmaceuticals, Inc.
Attention: Joseph Carrado, M.S., R.Ph.
Vice President, Clinical Regulatory Affairs
One Belmont Avenue, 11th Floor
Bala Cynwyd, PA 19004

Dear Mr. Carrado:

Please refer to your supplemental new drug application dated December 28, 2006, received December 29, 2006, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Enjuvia (synthetic conjugated estrogens, B) Tablets, 0.3 mg, 0.45 mg, 0.625 mg, and 1.25 mg.

We acknowledge receipt of your submission dated April 25, 2007.

This "Prior Approval" supplemental new drug application provides for adding a new strength, 0.9 mg tablets, and revising the lower limits in the API for 17α-dihydroequilenin and 17β-dihydroequilenin from 0.2% to 0.1%.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We note that SPL has not been submitted representing the content of your proposed labeling. By regulation [21 CFR 314.50(l), 314.94(d), and 601.14(b); Guidance for Industry: *Providing Regulatory Submissions in Electronic Format — Content of Labeling* (April 2005); http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s-0251-m000032-vol1.pdf], you are required to submit to FDA prescribing and product information (i.e., the package insert or label) in SPL format. Please submit PLR compliant SPL by (DATE).

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susan Jenney, Regulatory Health Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Hasmukh Patel

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