DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-405/S-023

APPROVAL LETTER

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

Dear Mr. Carrado:

Please refer to your supplemental new drug application dated December 13, 2004, received December 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AYGESTIN® (norethindrone acetate tablets, USP).

We also acknowledge receipt of your submissions dated December 13, 2004, March 21, April 11, 12, 13 and 26, 2005, April 14 and September 1, 2006, March 2 and July 2, 2007.

Your submission of March 2, 2007 constituted a complete response to our August 14, 2006 action letter.

This supplemental new drug application provides for (1) a change of the current formulation of AYGESTIN® to the ---------- formulation and (2) revised Physician and Patient Labeling and container and carton labeling.

We acknowledge your decision ---------- ----------

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the Package Insert, text for the Patient Package Insert submitted July 2, 2007) and submitted labeling (immediate container and carton labels submitted March 2, 2007).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this

submission "**FPL for approved supplement NDA 18-405/S-023**." Approval of this submission by FDA is not required before the labeling is used.

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 Ayoub Suliman, Pharm.D., Regulatory Health Project Manager, at (301) 796-0630.

Sincerely,

{See appended electronic signature page}

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

Scott Monroe, M.D.
Acting Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (text for the package insert, text for the patient package insert)

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
7/5/2007 08:02:17 AM

Scott Monroe
7/5/2007 10:06:52 AM