DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-045/S-015 **SUPPLEMENTAL NDA APPROVAL**

Duramed Pharmaceuticals, Inc.
Attention: Michele G. Walsh
Director, Clinical Regulatory Affairs
One Belmont Avenue, 11th Floor
Bala Cynwyd, PA 19004

Dear Ms. Walsh:

Please refer to your supplemental new drug application dated June 11, 2009, received June 12, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plan B® (levonorgestrel) tablets, 0.75 mg.

We acknowledge receipt of your submissions dated June 18, 22, 25, and 30, and July 7 (2), 8, and 9, 2009.

This supplemental new drug application provides for:

1. Over-the-counter (OTC) availability of Plan B® for women age 17 years and older. Plan B® reduces the chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control).
2. Prescription availability of Plan B® for women younger than age 17 years. Plan B® is emergency contraception for prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text (prescription package insert, carton label, inner blister card label, and consumer information leaflet).

PRESCRIPTION CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the prescription content of labeling [21 CFR 314.50(l)] 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 for the package insert (submitted July 9, 2009). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-045/S-015."

OTC CONTENT OF LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (consumer information leaflet submitted July 8, 2009).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels identical to the enclosed labeling (carton label and inner blister card label submitted July 8, 2009) as soon as they are available, but no more than 30 days after they are printed. These must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Please submit the labels and the OTC content of labeling electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 21-045/S-015**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

CARE℠ PROGRAM

We also acknowledge receipt of your submission dated July 7, 2009, describing the modified CARE℠ Program (see enclosure) that you will apply to Plan B®.

You must discuss any change to the CARE℠ Program with the FDA prior to implementation of the change.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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, please call Pamela Lucarelli, Regulatory Health Project Manager, at (301) 796-3961.

Sincerely,

{See appended electronic signature page}

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

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosures

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

/s/

Scott Monroe
7/10/2009 03:22:01 PM

Andrea Segal
7/10/2009 03:24:09 PM