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

4545 '01 MAY 16 P3:04

May 15, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane, Room 4-62
Rockville, MD 20857

Subject: **Docket Number 01P-0209/CP1**

Reference is made to a Citizen Petition filed May 1, 2001 by Duramed Pharmaceuticals, Inc. and assigned docket number 01P-0209/CP1 concerning the approval of a new tablet dosage form for Progesterone, USP.

We were recently informed by the Office of Regulatory Support of the Office of Generic Drugs that our petition failed to include a request for Waiver of Pediatric Studies. Thus, please find attached, prepared in accordance with FDA Guidance for Industry Recommendations for Complying with the Pediatric Rule (21 CFR 314.55 (a)), a request for a Waiver of Pediatric Studies.

This waiver request is submitted in four (4) copies.

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

Sincerely,

Annette Arlinghaus /for

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

01P-0209

SUP1

Duramed Pharmaceuticals, Inc.
Docket 01P-0209/CP 1
May 15, 2001

Request for Waiver of Pediatric Studies

Sponsor: Duramed Pharmaceuticals, Inc.
Cincinnati, Ohio

Product: Progesterone Tablets, USP, 100 mg and 200 mg strengths

Indications: For use in the prevention of endometrial hyperplasia in non-hysterectomized postmenopausal women who are receiving conjugated estrogens tablets. Also indicated for use in secondary amenorrhea.

Reason(s) for Waiving Pediatric Studies:

1. The drug is used for the treatment in postmenopausal females receiving conjugated estrogens therapy and has a second indication of secondary amenorrhea.
2. The new dosage form is unchanged except that it will be a solid oral tablet versus a soft gelatin oral capsule marketed by the innovator.

Justification for Waiving Pediatric Studies:

The drug is used for the treatment of adult females for the prevention of endometrial hyperplasia and is also used in the treatment of seconday amenorrhea.

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A. Arlinghaus

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