DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-945/S-037 & S-038

Duramed Pharmaceuticals, Inc.
Attn: Nicholas Tantillo
Senior Director, Regulatory Affairs
2 Quaker Road
Pomona, NY 10970

Dear Mr. Tantillo:

Please refer to your supplemental new drug applications dated June 30, 2004, received July 1, 2004, submitted under section 505(b) the Federal Food, Drug, and Cosmetic Act for the Diamox Sequels (acetazolamide sustained-release capsules) 500mg.

These supplemental new drug applications provide for the addition of (b)(4) ---- ---------- as an drug substance manufacturer; transfer of drug product manufacturing ----------atories, Pomona, NY, and Forrest, VA, and to Duramed Pharmaceuticals, Cincinnati, OH; change to hard gelatin capsules; revision to the drug product specification; and labeling revision.

Your submission of November 16, 2004, constituted a complete response to our November 4, 2004, action letter.

We completed our review of this application, as amended. These applications are 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 in content with the enclosed agreed upon label dated November 16, 2004. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

It is recommended that the **HOW SUPPLIED** section of the package insert to read "Store at controlled room temperature 20º to 25ºC (68º-77ºF)" without additional qualifications.

The final printed labeling (FPL) must be identical with the enclosed agreed upon labeling text for the package insert, dated November 16, 2004. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling is to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS

Word format. If formatted copies of all labeling pieces (i.e., package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising and Communications, HFD-42
Food and Drug Administration
5600 Fishers lane
Rockville, MD 20857

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, HFD-410
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Raphael R. Rodriguez, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic,
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure:

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

/s/

Wiley Chambers

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