DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-157/S-011, S-012, S-013, S-015

Medeva Pharmaceuticals
Attention: Robert B. Parker, Ph.D.
Senior Director, Regulatory Affairs
755 Jefferson Road
Post Office Box 1710
Rochester, New York 14603

Dear Dr. Parker:

Please refer to your supplemental new drug applications dated June 18, 1997, received June 23, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pediapred (prednisolone sodium phosphate, USP) Oral Solution.

We acknowledge receipt of your submissions dated September 24, 1998.

These supplemental new drug applications provide for the use of Pediapred Oral Solution for Pediatric Use (S-015), updated information in the CLINICAL PHARMACOLOGY section (S-012), and changes being affected to the WARNINGS section (S-011, S-013).

Please note that as a result of the Agency's effort to update labeling for all systemic glucocorticoids, various sections of the labeling has been revised and reformatted.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

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

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 19157/S-011, S-012, S-013, S-015." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Sharon Schmidt, M.S., Project Manager, at (301) 827-2536.

Sincerely,

John E. Hyde, Ph.D., M.D.
Acting Deputy Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFE-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure