ANDA 75-117 December 14, 2000

Ascent Pediatrics
Attention: William E. Brochu, Ph.D.
187 Ballardvale Street, Suite B125
Wilmington, MA 01887

Dear Sir:

This is in reference to your abbreviated new drug application dated April 21, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Orapred (Prednisolone Sodium Phosphate Oral Solution), 15 mg (base)/5 mL).

Reference is also made to your amendments dated February 3, September 18, November 19, December 11, and December 14, 1998; and February 11, March 10, July 14, September 21, September 29, October 16, October 23, and December 11, 2000. Reference is also made to the suitability petition submitted under Section 505(j)(2)(C) of the Act and approved on November 4, 1987, permitting you to file this ANDA for a drug product that differs in strength from the reference listed drug product (RLD).

The RLD referenced in your application, Pediapred Oral Solution of Medeva Pharmaceuticals, Inc., is subject to a period of patent protection which expires on December 22, 2002 (U.S. Patent No. 4,448,774, the '774 patent). Your application contains a patent certification to the '774 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on the patent. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Ascent Pediatrics (Ascent) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Ascent within the statutory forty-five day period.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The drug product, Orapred, can be expected to have the same therapeutic effect as that of an equivalent dose of the reference listed drug product upon which the Agency relied as the basis of safety and effectiveness.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies which may be identified.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research