NDA 74-973 January 24, 2000

Ascent Pediatrics, Inc.
Attention: William E. Brochu
187 Ballardvale St., Suite B125
Wilmington, MA 01887

Dear Sir:

This is in reference to your new drug application dated October 4, 1996, submitted pursuant to Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (Act), for Primsol Solution (Trimethoprim Hydrochloride Oral Solution, 50 mg (base)/5 mL).

Reference is also made to your amendments dated July 16, September 11, October 29, December 23, and December 31, 1997; January 8, March 16, March 31 April 15, May 6, May 8, June 1, and August 6, 1998; June 4, June 30, July 22, September 7, September 23, October 12, October 15, November 24, December 27, 1999; and January 10, 2000.

We have completed the review of this 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, Primsol Solution (Trimethoprim Hydrochloride Oral Solution, 50 mg (base)/5 mL) can be expected to have the same therapeutic effect as that of the 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 application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this 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 that 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.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research