ANDA 75-099 June 28, 2002

Morton Grove Pharmaceuticals, Inc.
Attention: Yogita Desai
6451 West Main Street
Morton Grove, IL 60053

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 24, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Prednisolone Sodium Phosphate Oral Solution, 5 mg (base)/5 mL.

Reference is also made to your amendments dated January 25, April 24, and June 25, 2002.

The listed drug product (RLD) referenced in your application, Pediapred® Oral Solution of Celltech 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 Paragraph IV Certification to this 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 this patent or that this patent is otherwise invalid. Section 505(j)(5)(B)(iii) of the Act provides that approval of this abbreviated new drug application shall be made effective immediately, unless an action is brought against Morton Grove Pharmaceuticals, Inc. for the infringement of the patent. You have notified the agency that the former NDA holder initiated a patent infringement action against you in the United States District Court for the Northern District of Illinois (Medeva Pharmaceuticals Manufacturing, Inc., et al. v. Morton Grove Pharmaceuticals, Inc., Civil Action No. 00 C 1689).

In your January 25, 2002 amendment you informed the agency that Celltech Manufacturing Inc. (formerly known as Medeva Pharmaceuticals Manufacturing, Inc., and successor in interest to Fisons Investments, Inc.) and Celltech Pharmaceuticals, Inc. (formerly known as Medeva Pharmaceuticals, Inc.) (collectively

"Celltech") reached an agreement to settle the '774 Patent Litigation and that Morton Grove was granted a license from Celltech Americas, Inc. to make, use, offer to sell, sell and/or otherwise practice any invention claimed in the '774 patent. You informed the agency that the parties settled the patent infringement lawsuit on November 15, 2001, and that the litigation was dismissed by the court on January 4, 2002.

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 Division of Bioequivalence has determined your Prednisolone Sodium Phosphate Oral Solution, 5 mg (base)/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug Pediapred® Oral Solution, 5 mg (base)/5 mL.

With respect to 180-day generic drug exclusivity, we note that Morton Grove Pharmaceuticals, Inc. was the first applicant to submit a substantially complete ANDA with a Paragraph IV Certification to the '774 patent for this drug product. Therefore, with this approval Morton Grove Pharmaceuticals, Inc. is eligible for 180-days of market exclusivity as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505 (j)(5)(B)(iv) of the Act. Such exclusivity will begin to run from the date Morton Grove Pharmaceuticals, Inc. begins commercial marketing of the drug product.

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of this product.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the Agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710).

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 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 FDA 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 FDA 2253 at the time of their initial use.

Sincerely yours,

/S/

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