ANDA 76-200 March 19, 2002

CorePharma LLC
Attention: Mukteeshwar Gande
215 Wood Avenue
Middlesex, NJ 08846

Dear Sir:

This is in reference to your abbreviated new drug application dated July 2, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Acetaminophen Extended-release Tablets, 650 mg.

Reference is also made to your amendments dated August 20, September 12, October 18, November 5, and December 7, 2001; and February 5, 2002.

The listed drug referenced in your application, Tylenol Arthritis Pain Extended-release Tablets of McNeil Consumer Products Company, is subject to periods of patent protection which expire on July 27, 2007 (U.S. Patents No. 4,820,522 and 5,004,613) and on November 6, 2007 (U.S. Patent no. 4,968,509), e.g., the ‘522, ‘613, and 509 patents, respectively. Your application contains patent certifications to each of these patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents will not be infringed by your manufacture, use, sale, or offer for sale of the proposed drug product. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action is brought for infringement of one or more of the patents which are the subject of the certifications. This action must be brought before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received by the NDA and patent holders. You have notified FDA that CorePharma LLC has complied with the requirements of Section 505(j)(2)(B) of the Act, and that no action for patent infringement was brought against CorePharma LLC 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 Over-The-Counter (OTC) labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Acetaminophen Extended-release Tablets, 650 mg to be bioequivalent to the listed drug (Tylenol® Arthritis Pain Extended-release Tablets, 650 mg, of McNeil Consumer Products Company).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

Dissolution testing should be conducted in
_____
_____.
The test product should meet the following "interim" specifications:

_____
_____
_____

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

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.

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 that may be identified.

Sincerely yours,

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