

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

76-200/S-001

CORRESPONDENCE

April 18, 2002

Office of Generic Drugs
CDER, Food and Drug Administration
Metro Park North
7500 Standish Place, Room 150
Rockville, MD 20855

ANDA NO. 76-200 REF NO. SCS-001-AI
ANDA SUPPL FOR Control Rev

CHANGES BEING
EFFECTED

**Re: Acetaminophen Extended Release Tablets 650 mg, ANDA # 76-200
Finalized "interim" Dissolution Specifications**

Dear Director:

Please find enclosed a "Changes Being Effectuated - 0 Days Supplement" to our-approved ANDA for Acetaminophen Extended Release Tablets 650 mg, ANDA # 76-200.

We completed first three validation batches successfully and compiled here dissolution profile for all three batches as per the requirement in the approval letter dated March 19, 2002. Please note that FDA suggested "interim" dissolution specification has been finalized and the suggested specification has been incorporated into the stability and quality control program.

Corepharma has submitted an additional copy of this supplemental application, as required under 314.71(b), to the Food and Drug Administration, New Jersey District Office. We hereby certify that this additional copy (field copy) is a true copy of the supplemental application.

Please direct any written communication regarding this submission to me at the above address. If you need to call or fax me, my telephone number is (732) 868-1090 and (732) 868 1091 (fax).

Sincerely,



Mukteeshwar Gande, M.S., R.Ph.
Vice President

RECEIVED

APR 19 2002

OGD / CDER