CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

76-200/S-002;S-003;S-004

APPROVAL LETTER

ANDA 76-200/S-002, S-003, S-004

Corepharma LLC
Attention: Mukteeshwar Gande, M.S., R.Ph.
215 Wood Avenue
Middlesex, NJ 08846

DEC 3 2002

Dear Madam:

This is in reference to your supplemental new drug applications, dated May 17, 2002, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug applications for Acetaminophen Extended Release Tablets 650 mg.

Reference is also made to your amendment dated September 18, 2002.

These supplemental applications, submitted as "Changes Being Effected in 30 days", provide for the following changes:

S-002 [redacted]

S-003 [redacted]

S-004 The addition of a bulk packaging configuration.

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

APPEARS THIS WAY
ON ORIGINAL

The material submitted is being retained in our files.

Sincerely yours,

12/2/02

for Florence S. Fang
Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL