CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

76-200/S-001

APPROVAL LETTER

ANDA 76-200/S-001

OCT 15 2002

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

Dear Madam:

This is in reference to your supplemental new drug application, dated April 18, 2002, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Acetaminophen Extended Release Tablets, 650 mg.

This supplemental application, submitted as "Changes Being Effected", provides for the following change:

S-001 Confirmation of FDA suggested "interim" dissolution specification

We have completed the review of this supplemental application and it is 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.

The material submitted is being retained in our files.

Sincerely yours,

10/8/02

for

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