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APPLICATION NUMBER:

76-200/S-005

APPROVAL LETTER

AUG 11 2004

✓ ANDA 76-200/S-005

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

Dear Sir:

This is in reference to your supplemental new drug application (ANDA) dated ⁽⁴⁵⁾ ~~May 21~~ ^{MARCH 27}, 2004, 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.

REF is also made to your amendment on MAY 21, 2004 (24)

The supplemental application, submitted as "Supplement - Changes Being Effected in 30 days" provides for:

S-005: _____

(_____) at:

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

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

The materials submitted are being retained in our files.

Sincerely yours,

R.E. Adams for

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