

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

76-200/S-005

**ADMINISTRATIVE
DOCUMENT(S)**

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Application : ANDA 76200/005 Sponsor: COREPHARMA
Org Code : 600 215 WOOD AVE
Priority : MIDDLESEX, NJ 08846

Stamp Date : 24-MAR-2004 Brand Name :
PDUFA Date : Estab. Name: ACETAMINOPHEN
Action Goal : Generic Name:
District Goal: 24-AUG-2004 Dosage Form: (EXTENDED-RELEASE TABLET)
Strength : 650 MG

FDA Contacts: C. PALAT III Project Manager (HFD-615)

Overall Recommendation: ACCEPTABLE on 27-APR-2004 by J. D AMBROGIO (HFD-322)
301-827-9049

Establishment : CFN : FEI :

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DMF No: AADA:

Responsibilities: _____

Profile : TCM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 27-APR-04
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

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CORRESPONDENCE

