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RESEARCH**

APPLICATION NUMBER:

022503Orig1s000

PROPRIETARY NAME REVIEW(S)



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: May 13, 2010

To: Badrul Chowdhury, M.D., Director
Division of Pulmonary, Allergy, and Rheumatology Products

Through: Zachary Oleszczuk, Pharm.D., Acting Team Leader
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From: Tara Turner, Pharm.D., Safety Evaluator
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Subject: Proprietary Name Review

Drug Name(s): (b) (4)
(Metaxalone) Tablets
640 mg

Application Type/Number: NDA 022503

Applicant: CorePharma LLC

OSE RCM #: 2009-2136; 2010-533

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22503	ORIG-1	COREPHARMA LLC	(b) (4) 640MG (METAXALONE)

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/s/

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05/13/2010

CAROL A HOLQUIST
05/13/2010