

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**22-351**

**PHARMACOLOGY REVIEW(S)**



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

## PHARMACOLOGY/TOXICOLOGY REVIEW AND EVALUATION

NDA NUMBER: 22-351

SERIAL NUMBER: 000

DATE RECEIVED BY CENTER: Sept 30, 2008

PRODUCT: Colchicine

INTENDED CLINICAL POPULATION: Treatment of acute gout flares

SPONSOR: Mutual Pharmaceutical Co., Inc.

DOCUMENTS REVIEWED: eCTD Module 4

REVIEW DIVISION: Division of Anesthesia, Analgesia, and Rheumatology Drug Products (HFD-170)

PHARM/TOX REVIEWER: L. Steven Leshin, DVM, PhD

PHARM/TOX SUPERVISOR: Adam Wasserman, PhD

DIVISION DIRECTOR: Bob Rappaport, MD

PROJECT MANAGER: Margarita Tossa

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/s/

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Lawrence Leshin  
6/5/2009 04:01:00 PM  
PHARMACOLOGIST

Adam Wasserman  
6/5/2009 05:25:48 PM  
PHARMACOLOGIST  
I concur with Dr. Leshin's recommendations.