CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-351

OTHER REVIEW(S)

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications

****PRE-DECISIONAL AGENCY MEMO****

Date: July 06, 2009

To: Margarita Tossa- Regulatory Project Manager
Matthew Sullivan – Regulatory Project Manager
Division of Anesthesia, Analgesia, and Rheumatology Products (DAARP)

From: Mathilda Fienkeng – Regulatory Review Officer
Division of Drug Marketing, Advertising, and Communications (DDMAC)

Through: Andrew Haffer – Regulatory Review Officer
Division of Drug Marketing, Advertising, and Communications (DDMAC)

Subject: **DDMAC draft labeling comments**
NDA 22-351 **COLCRYS**™ (Colchicine Tablets, USP) for Oral use

DDMAC has reviewed the proposed product labeling (PI), for **COLCRYS**™ (Colchicine Tablets, USP) for Oral use (Colcrys), submitted for consult on November 19, 2008.

The following comments for the Professional section of the label are provided using the updated proposed PI sent via email on June 30th 2009 by Margarita Tossa. Comments on the patient labeling (PPI) section and/or MedGuide will be sent separately when DDMAC receives the proposed labeling from the Review Division as discussed in our June 30, 2009 meeting. If you have any questions about DDMAC's comments, please do not hesitate to contact us.

17 Page(s) Withheld

_____ § 552(b)(4) Trade Secret / Confidential

√ § 552(b)(4) Draft Labeling

√ § 552(b)(5) Deliberative Process

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/s/

Mathilda Fienkeng
7/6/2009 03:30:44 PM
DDMAC PROFESSIONAL REVIEWER