



December 18, 2009

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research
Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20933

Re: Removal of unapproved colchicine

Dear Dr. Woodcock,

The American College of Rheumatology recently became aware that unapproved colchicine is being forced off the market. Unapproved colchicine has been used for over 200 years as an inexpensive pain-reliever and anti-inflammatory for the millions of patients suffering from gout. The removal of an inexpensive, safe and effective drug used to treat acute gout patients will have a costly affect on these patients' access to a drug therapy. The College strongly encourages the Food and Drug Administration to grandfather unapproved colchicine and grant market approval to colchicine so that patients can continue to access this vital inexpensive treatment.

URL Pharma, Inc. recently received market approval for COLCRYS®. With this approval, the price of the drug has increased from approximately 10 cents per tablet to five dollars per tablet. This increase will put the drug out-of-reach of many patients. Generally, market approval would provide market exclusivity to the new drug (for a certain period of time) to the pharmaceutical company. However in the case of colchicine, the drug has been produced for centuries by a number of manufacturers. Considering colchicine's history, unapproved colchicine should be recognized as identical, related, or similar status to an approved drug.

According to the Compliance Policy Guide, the FDA will evaluate drugs (case-by-case) to determine if justification exists to allow for continued marketing after FDA determines that a product is being marketed illegally. The ACR requests that the FDA review colchicine and allow manufacturers to continue drug production so patients can afford this important treatment. One of the deciding factors in FDA policy is "the burden on affected parties of immediately removing the product from the market." Removal of unapproved colchicine will be an extreme cost burden to patients who take colchicine for gout prophylaxis increasing medication cost from approximately \$6/month to \$300/month. Most only take one a day for prophylaxis suggest \$3 to \$150

In light of the recently FDA approval of COLCRYS®, the ACR respectfully requests FDA review and provide market approval of unapproved colchicine. The availability of unapproved

colchicine will provide access to drug therapies for millions of acute gout patients and assist in reducing health care costs for patients and Medicare.

This letter is being sent to you based on numerous comments from ACR members. The entire US ACR membership and leadership is very concerned that colchicine will be priced beyond the abilities of many patients. I would like an opportunity to discuss this situation with you in depth either in person or via telephone. Please feel free to contact me at your convenience at (214) 540-0646 or via e-mail at arthdoc@aol.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Stanley Cohen', with a long horizontal flourish extending to the right.

Stanley Cohen, MD
President, American College of Rheumatology