DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-273

Mallinckrodt Inc.
Attention: Melissa D. Henry
Manager, Regulatory Affairs
675 McDonnell Boulevard
Hazelwood, MO 63042

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 9, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for TussiCaps® (Hydrocodone Polistirex and Chlorpheniramine Polistirex, equivalent to 5 mg Hydrocodone Bitartrate and 4 mg Chlorpheniramine Maleate and 10 mg Hydrocodone Bitartrate and 8 mg Chlorpheniramine Maleate, respectively) Extended-release Capsules.

Reference is also made to your amendments dated July 12, 2005; and March 31, April 7, May 30, and October 3, and October 20, 2006; and January 18, April 25, July 17, and July 24, 2007.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved. The Division of Bioequivalence has determined your TussiCaps® (Hydrocodone Polistirex and Chlorpheniramine Polistirex, equivalent to 5 mg Hydrocodone Bitartrate and 4 mg Chlorpheniramine Maleate and 10 mg Hydrocodone Bitartrate and 8 mg Chlorpheniramine Maleate) Extended-release Capsules, can be expected to have the same therapeutic effect as that of the reference listed drug, Tussinonex Pennkinetic (Hydrocodone Polistirex and Chlorpheniramine Polistirex, equivalent to 5 mg Hydrocodone Bitartrate and 4 mg Chlorpheniramine Maleate per 5 mL and 10 mg Hydrocodone Bitartrate and 8 mg Chlorpheniramine Maleate per 5 mL, respectively)Extended-release Suspension, of UCB Inc., upon which the Agency relied as the basis of safety and effectiveness. Your dissolution testing should be

incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
9/24/2007 08:00:48 AM
for Gary Buehler