DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078907

Mallinckrodt Inc.
Attention: Melissa Henry
Director, Regulatory Affairs
675 McDonnell Blvd.
Hazelwood, MO 63042

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 29, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oral Transmucosal Fentanyl Citrate, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg.

Reference is also made to your amendments dated September 28, 2007; March 28, May 16, July 7, July 18, and September 10, 2008; and March 13, April 9, May 15, June 2, June 24, July 17, and August 3, 2009.

We have completed the review of this ANDA, including the Risk Management Plan (RMP), as amended, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling.

The following elements of the Risk Management Plan have been identified as being essential to the safe and effective use of your drug product.

- Medication Guide
- Plan to Monitor
- Welcome Kit: Fanny Pack
  Lock & Keys
  Child Safety Lock
  Child Resistant Temporary Storage Container
  Home Warning Stickers
  Daily Diary
  Brightly Colored Warning Flyers

- The following components will not be approved as part of the Risk Management Plan. However, you may distribute them as promotional materials, to the extent that the content of the materials is in compliance with the Act and implementing regulations.

    - Refrigerator Magnets
    - Children's Booklet
    - Diary Marker
    - Patient Safety Video

Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Oral Transmucosal Fentanyl Citrate, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Actiq, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg and 1600 mcg, respectively, of Cephalon, Inc. 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. Additionally, any proposed change in the RMP must be discussed with FDA prior to institution. FDA will determine whether the proposed change is subject to FDA approval before implementation.

In accordance with section 505-1(i) of the FDCA, an abbreviated new drug application (ANDA) is required to have a Risk Evaluation & Mitigation Strategy (REMS) if the applicable listed drug has an approved REMS. The reference listed drug, Actiq, in addition to other oral transmucosal drug products containing fentanyl, is being required to implement a REMS. Pursuant to section 505-1(i) of the FDCA, a drug that is the subject of an ANDA and the listed drug it references must use a single shared system for elements to assure safe use unless FDA waives that requirement. We suggest that you contact Cephalon to pursue a single shared system for the elements to assure safe use in your future REMS.

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 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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence – SPL for Approved ANDA 078907"***.

Sincerely yours,

{See appended electronic signature page}

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

Attachment: Critical Elements of the Risk Management Plan (RMP)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-78907	ORIG-1	TYCO HEALTHCARE MALLINCKRODT	FENTANYL CITRATE

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
10/30/2009
Deputy Director, for Gary Buehler