DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-947/S-006

Cephalon, Inc
41 Moores Road
PO Box 4011
Frazer, PA 19355

Attention: Penny S. Levin, M.S.
Director, Regulatory Affairs

Dear Ms. Levin:

Please refer to your supplemental new drug application (sNDA) dated December 5, 2007, received December 6, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for FENTORA (fentanyl buccal tablet), 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, and 800 mcg.

This supplemental new drug application provides for revisions to the package insert, Medication Guide and carton container labeling to enhance the safety information.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format and carton labeling submitted on December 5, 2007, and with the following editorial revision to the Medication Guide as agreed upon in an email exchange with Dr. Eric Floyd of Cephalon on January 16, 2008.

> **What are the possible or reasonably likely SIDE EFFECTS of FENTORA?**
>
> Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

In addition we note that the following words were inadvertently omitted from the agreed-upon text for the BOX WARNING in the version you submitted to us for review. We have inserted this language into the enclosed package insert.

> *FENTORA* is indicated only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

CONTENT OF LABELING

We will transmit the content of labeling in SPL format, as amended, to the National Library of Medicine for public dissemination.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton container labels that are identical to the December 5, 2007, submitted carton container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved sNDA 21-947/S-006**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kimberly Compton, Regulatory Project Manager, at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert (content of labeling)
Medication Guide
Carton labeling

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

/s/

Sharon Hertz
2/7/2008 05:45:45 PM
signing for Bob Rappaport, M.D.