DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-947/S-002

Cephalon, Inc
c/o CIMA Labs
41 Moores Road
Frazer, PA 19355

Attention: Carol S. Marchione
Senior Director, Regulatory Affairs

Dear Ms. Marchione:

Please refer to your supplemental new drug application dated November 2, 2006, received November 3, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for FENTORA (fentanyl buccal tablet), 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg.

We acknowledge receipt of your submissions dated February 1, and March 1 and 2, 2007.

This supplemental new drug application provides for the addition of a 300-mcg strength dose.

We have completed our review of this application, as amended and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the Medication Guide, immediate container and carton labels).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text for the package insert and Medication Guide. For administrative purposes, designate this submission "**Content of Labeling for approved NDA 21-947/S-002**." Upon receipt and verification that the content of labeling in SPL format is identical to the approved labeling text, we will transmit that version to the National Library of Medicine for public dissemination.

Please electronically submit final printed carton and container (blister) labels that are identical to the enclosed carton and immediate container labels (submitted March 3, 2007). Alternatively, you may submit 12 paper copies of the carton and container labels as soon as they are available but not more than 30 days after they are printed. Individually mount 6 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission **"Final Printed Carton and Container Labels for approved NDA 21-947/S-002."** Approval of this submission by FDA is not required before the labeling is used.

We acknowledge your amendments dated March 1, 2007, committing to the following:

1. To reassess the relative standard deviation (RSD) of the in-process tablet content uniformity testing after one year of production of the 300-mcg strength tablet (commercial scale). After your reassessment, you will either tighten the RSD to NMT ------ or provide the FDA with justification for not tightening the RSD from the current NMT ------.

2. To provide, within 3 months of approval of this supplement, Batch Analysis Data on the commercial scale, white, 300-mcg tablet strength.

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

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

Your product is approved with a shelf-life of 24 months.

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

Enclosure

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

/s/

Bob Rappaport

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