DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

N 21-947/S-001

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 (sNDA) dated October 25, 2006, received October 27, 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, 300 mcg, 400 mcg, 600 mcg, and 800 mcg.

We acknowledge receipt of your submissions dated December 7, 2006, and March 8, and April 17 and 25, 2007.

This supplemental new drug application provides for the inclusion of language requested in the Agency's September 24, 2006, Supplement Request Letter.

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 (submitted April 25, 2007), text for the Medication Guide (submitted April 25, 2007), and immediate container and carton labels (submitted March 3 and April 25, 2007).

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-001**." 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. 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-001." Approval of this submission by FDA is not required before the labeling is used.

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

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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