DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-747/S-027

Cephalon, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19355

Attention: Carol S. Marchione
Sr. Director, Regulatory Affairs

Dear Ms. Marchione:

Please refer to your supplemental new drug application dated September 1, 2006, received September 1, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actiq (oral transmucosal fentanyl citrate).

We acknowledge receipt of your submissions dated October 23, December 4, 12, 14 and 15, 2006.

This supplemental new drug application provides for the use of Actiq (oral transmucosal fentanyl citrate) for the management of breakthrough cancer pain in patients 16 and older with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

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

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 20-747/S-027." 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.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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}

Sharon H. Hertz, M.D.
Deputy 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/

Sharon Hertz

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