DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-747/S-023

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 March 3, 2006, received March 6, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Actiq (oral transmucosal fentanyl citrate).

We acknowledge receipt of your submissions dated August 1, 14, 22 and 30, 2006.

This supplemental new drug application provides for the conversion of the Patient Package Insert (also referred to as Patient Leaflet) to a Medication Guide, relabeling of the brand product as a generic, and all corresponding labeling for the generic version of the product, including the RiskMAP.

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 and with the minor editoral revision listed below.

> In the Pharmacology subsection of the CLINICAL PHARMACOLOGY AND PHARMACOKINETICS section, there is a typo in the sentence cited below. Please correct it as indicated by the strikethrough/highlighting below.
>
> > Like all pure opioid agonists analgesics, with increasing doses there is increasing analgesia, unlike with mixed agonist/antagonists or non-opioid analgesics, where there is a limit to the analgesic effect with increasing doses.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated to the enclosed labeling (text for the brand and generic package insert, text for the brand and generic Medication Guide, brand and generic immediate container [blister] and carton labels and generic handle tags) and the submitted labeling (RiskMAP submitted August 30, 2006).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this

submission "**FPL for approved supplement NDA 20-747/S-023**." 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 20857

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, MD
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures-
Brand and generic Package Insert
Brand and generic Medication Guide
Brand and generic blister labels
Brand and generic carton labels
Generic handle tags

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

9/6/2006 01:55:30 PM