DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-747/S-011

Cephalon, Inc.
145 Brandywine Parkway
West Chester, PA 19380-4245

Attention: Carol S. Marchione
Senior Director, Regulatory Affairs

Dear Ms. Marchione:

Please refer to your supplemental new drug application dated March 6, 2002, received March 8, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actiq (Oral Transmucosal Fentanyl Citrate).

We acknowledge receipt of your submission dated March 26, 2002.

This "Changes Being Effected" supplemental new drug application provides for a revised "Information for Patients and Their Caregivers" subsection of the "PRECAUTIONS" section of the package insert and a revised patient leaflet. A statement advising diabetic patients that Actiq contains 2 grams of sugar per unit is added.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted March 26, 2002.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs* (January 1999). For administrative purposes, the submission should be designated "FPL for approved supplement NDA 20-747/S-011." Approval of the submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kimberly Compton, Regulatory Project Manager, at (301) 827-7432.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

Cynthia McCormick

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