EXHIBIT 1009

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA20-747/S-017

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

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

Dear Ms. Marchione:

Please refer to your supplemental new drug application dated March 24, 2004, received March 25, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actiq® (oral transmucosal fentanyl citrate).

This "Changes Being Effected" supplemental new drug application provides for changes to the PRECAUTIONS section of the package insert and patient leaflet and the ADVERSE REACTIONS-Post Marketing Experience section to address the association of Actiq with occurrences of dental caries, tooth loss and gum line erosion.

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

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, HFD-410
FDA
5600 Fishers Lane
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) 827-7432.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care and
Addiction Drug 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/

Rigoberto Roca
9/24/04 06:14:53 PM
for Bob Rappaport, M.D.