DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-747/S-019

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

Attention: Carol Marchione
Senior Director, Regulatory Affairs

Dear Ms. Marchione:

Please refer to your supplemental new drug application dated November 19, 2004, received November 19, 2004, 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 January 28 and 31, March 8, April 13, May 10, and August 9, 2005.

Your submission of May 10, 2005, constituted a complete response to our March 18, 2005, action letter.

This supplemental new drug application provides for a sugar-free formulation of the drug product.

We have completed our review of this application, as amended and it is approved, effective on the date of this letter, and for use as recommended in the agreed-upon labeling text with the following minor editorial revision as agreed upon in your email of September 1, 2005.

In Figure 2 of the package insert, change the line from time point 0 to 15 mins to a dashed line.

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the enclosed labeling (text for the package insert, text for the patient package insert), and submitted labeling (immediate container and carton labels submitted May 10, 2005). This revision are terms of the approval of this application.

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-019.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you of your agreements, as per your September 9, 2005, correspondence, to submit a CBE-30 supplement providing for the conduct of crystallinity testing of the isomalt excipient and to market

this sugar-free formulation of the Actiq drug product with an 18-month expiry date for the drug product.

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

Enclosures

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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