



NDA 20-747/S-018

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

Attention: Carol S. Marchione  
Senior Director, Regulatory Affairs

Please refer to your supplemental new drug application dated September 8, 2004, received September 9, 2004, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Actiq® (oral transmucosal fentanyl citrate).

This supplemental new drug application provides for a change to the blister label to provide clarification as to where to cut open the package.

We have completed our review of this application 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 submitted labeling (blister label, submitted September 8, 2004.)

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-747/S-018." 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, HF-2  
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 Anesthetic, Critical Care, and  
Addiction Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/

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Bob Rappaport  
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