



Food and Drug  
Administration  
Rockville MD 20857

NDA 20-747/S-010

Anesta Corporation  
C/O Cephalon, Inc.  
145 Brandywine Parkway  
West Chester, PA 19380-4245

Attention: Kenneth L. White, Pharm.D.  
Vice President, Regulatory Affairs

Dear Dr. White:

Please refer to your supplemental new drug application dated January 28, 2002, received January 29, 2002, 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 revisions to the **PRECAUTIONS** section of the Package Insert and to the Patient leaflet.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

1. In the package insert, remove the “°” (degrees) symbol after the 2.51 number from the second sentence of the 5<sup>th</sup> paragraph of the “**Pharmacokinetic, absorption** subsection of the **CLINICAL PHARMACOLOGY** section.
2. The following revisions pertain to the Patient Leaflet.
  - a. Underline the word “not” to read “If the person is not awake and alert...” in the first sentence of the “If Someone Accidentally Takes Actiq” subheading in the black box.
  - b. Underline and bold the word “not” to read “You should **not** use Actiq if you are having short term...” and “You should **not** use Actiq unless you have breakthrough cancer...” in the first and second sentence of “When Not To Use Actiq” subsection.
  - c. Underline the word “not” to read “**If the person is not awake and alert...**” in the third bullet of the “What To Do If A Child Or Adult Accidentally Takes Actiq” *subsection*.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert and patient leaflet submitted January 28, 2002). These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. 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-010." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

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 Parinda Jani, Acting Chief, Project Management Staff, at (301) 827-7410.

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

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/s/

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Cynthia McCormick  
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