DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-747/S-009

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

Attention: Carol S. Marchione
Senior Director, Regulatory Affairs

Dear Ms. Marchione:

Please refer to your supplemental new drug application (NDA) dated January 16, 2002, received January 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actiq (oral transmucosal fentanyl citrate).

This supplemental new drug application proposes a change to the Risk Management Plan that was approved in our letter of November 4, 1998, specifically, to change the name used to refer to the portion of the sales force that markets the drug product.

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

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.
Acting 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/

Celia Winchell
1/29/03 11:23:23 AM
for Bob A. Rappaport, M.D., Acting Division Director