DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-747/S-006

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 March 5, 2001, received March 6, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Actiq (oral transmucosal fentanyl citrate).

We acknowledge receipt of your submissions dated March 21, 2001.

This supplemental new drug application provides for a revision in the lasered wording on the Actiq handle.

We have completed the review of this supplemental application, as amended, and it approved effective on the date of this letter.

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 Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

{See appended electronic signature page}

Dale Koble, Ph.D.
Acting Chemistry Team Leader
Division of Anesthetic, Critical Care, and
Addiction Drug Products
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research