DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-777/S-003

Anesta AG
(c/o) Cephalon, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19355

Attention: James M. Ciciriello
Director, Regluatory Affairs

Dear Mr. Ciciriello:

Please refer to your supplemental new drug application dated October 10, 2007, received October 11, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AMRIX™ (cyclobenzaprine hydrochloride) extended-release capsules.

This "Changes Being Effected" supplemental new drug application provides for changes to the immediate container label for the AMRIX 30-mg trade bottle.

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 enclosed final printed container label submitted on October 10, 2007.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

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 Kathleen Davies, Regulatory Project Manager, at (301) 796-2205.

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

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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