CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-947

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Cephalon, Inc
c/o CIMA Labs
41 Moores Road
Frazer, PA 19355

Attention: Carol S. Marchione
Senior Director, Regulatory Affairs

Dear Ms. Marchione:

Please refer to your new drug application (NDA) dated August 31, 2005, received August 31, 2005, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for FENTORA (fentanyl buccal tablet), 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg.

We acknowledge receipt of your submissions dated September 9, January 5, 6, 20, February 22, 24, March 2, 13, 24, 29, April 7 (2), 24, May 11, 23, 26 (2), June 2, 5, 16 (2), 21, 23, 26 (2), 27 and 29, 2006.

We have completed our review of this application, as amended, with draft labeling, and it is approvable. Before the application may be approved, however, it will be necessary for you to submit for review your final Risk Minimization Action Plan (RiskMAP) designed to help ensure the safe use of FENTORA.

In addition, it will be necessary for you to submit final printed labeling (FPL) for the drug. The labeling must be identical in content to the enclosed labeling text for the package insert and immediate container (blister) and carton labels. The Medication Guide should be revised to improve the graphics by using pictures or diagrams that more accurately depict the steps of product use.

Please submit the 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.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Kimberly Compton, Regulatory Project Manager, at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures

Package Insert
Medication Guide
Blister and Carton Labels

36 Page(s) Withheld

_____ Trade Secret / Confidential

✓ Draft Labeling

_____ Deliberative Process

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
6/29/2006 02:54:30 PM