DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-671/S-015

Skye Pharma Inc.
10450 Science Center Drive
San Diego, CA 92121

Attention: Paula Adams, Ph.D.
Director, Regulatory Affairs

Dear Dr. Adams:

Please refer to your supplemental new drug application dated August 14, 2006, received August 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DepoDur (morphine sulfate extended-release liposome injection).

We also acknowledge receipt of your submissions dated January 29, and 31, and February 8, 2007.

This supplemental new drug application provides for the addition of adverse event information to the package insert, and amplifying the warning language regarding intrathecal administration of DepoDur.

We have completed our review of this application, as amended, and it is approved effective on the date of this letter for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert, and immediate container and carton labels (submitted January 31, 2007).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text for the package insert. For administrative purposes, designate this submission **"Content of Labeling for approved NDA 21-671/S-015."** Upon receipt and verification that the content of labeling in SPL format is identical to the approved labeling text, we will transmit that version to the National Library of Medicine for public dissemination.

Please electronically submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels (submitted January 31, 2007). Alternatively, you may submit 12 paper copies of the carton and container labels as soon as they are available but no more than 30 days after they are printed. Individually mount 6 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission **"Final Printed Carton and Container Labels for approved NDA 21-671/S-015."** Approval of this submission by FDA is not required before the labeling is used.

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

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

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 Matt Sullivan, Regulatory Project Manager, at 301-796-1245.

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

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Rigoberto Roca
2/15/2007 04:50:25 PM
for Bob Rappaport, M.D.