DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-671/S-019 **SUPPLEMENT APPROVAL**

Pacira Pharmaceuticals Inc.
10450 Science Center Drive
San Diego, CA 92121

Attention: Glendon Knott
Senior Regulatory Affairs Associate

Dear Mr. Knott:

Please refer to your supplemental new drug application dated September 28, 2007, received October 1, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DepoDur (morphine sulfate extended-release liposome injection).

This supplemental new drug application provides for additional warning and adverse event information regarding delayed respiratory depression due to inadvertent intrathecal leakage of DepoDur, as requested in our March 28, 2007, supplement request letter.

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 agreed-upon labeling text, which includes the minor revision listed below.

> Replace the first sentence under DESCRIPTION with the following:
>
> DepoDur (morphine sulfate extended-release liposome injection) is a sterile suspension of multivesicular liposomes using proprietary DepoFoam® formulation technology containing morphine sulfate, intended for epidural administration.

As soon as possible, but no later than 14 days from 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-019."** 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.

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/

Bob Rappaport

12/14/2007 10:45:24 AM