DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

SUPPLEMENTAL NDA APPROVAL

NDA 21-671/S-020

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

Attention: Glenn Sherman, Ph.D.
Director, Regulatory Affairs

Dear Dr. Sherman:

Please refer to your supplemental new drug application (sNDA) dated May 14, 2008, received May 16, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DepoDur (morphine sulfate extended-release liposome injection).

Reference is also made to your amendment dated May 1, 2009, which constituted a complete response to our November 15, 2008, action letter.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY, WARNINGS, PRECAUTIONS, AND DOSAGE AND ADMINISTRATION** sections of the Package Insert.

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-671/S-020."**

LETTERS TO HEALTH CARE PROFESSIONALS

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Christopher Hilfiger, Regulatory Project Manager, at (301) 796-4131.

Sincerely,

{See appended electronic signature page}

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

Enclosure – Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21671	SUPPL-20	PACIRA PHARMACEUTICALS INC	DEPODUR

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

/s/

BOB A RAPPAPORT
09/25/2009