DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022534

NDA APPROVAL

Sun Pharma Global FZE
Attention: Karin Kook
Managing Director, Salamandra, LLC
U.S. Agent for Sun Pharma
One Bethesda Center
4800 Hampden Lane, Suite 900
Bethesda, Maryland 20814-2998

Dear Ms. Kook:

Please refer to your New Drug Application (NDA) dated April 23, 2009, received April 23, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for DOCEFREZ™ (docetaxel) for Injection, 20 mg/vial and 80 mg/vial.

We acknowledge receipt of your amendments dated March 10, 2010; April 23, 2010; October 19, 2010; October 25, 2010; November 3, 2010; December 21, 2010; April 8, 2011; April 13, 2011; April 15, 2011; April 22, 2011, April 26, 2011; April 28, 2011; April 29, 2011; May 2, 2011 and May 3, 2011.

Please also refer to our tentative approval letter dated February 23, 2010.

This new drug application provides for the use of provides for the use of DOCEFREZ™ (docetaxel) for Injection, 20 mg/vial and 80 mg/vial for locally advanced or metastatic breast cancer, locally advanced or metastatic non-small cell lung cancer and hormone refractory metastatic prostate cancer.

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

A 30-month expiration dating period is granted for the drug product, when stored at 2°- 8°C (36°F-46°F) and protected from light.

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the

patient package insert, Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.
The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your April 15, 2011; April 22, 2011 and April 29, 2011, submissions containing final printed carton and container labels.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

METHODS VALIDATION

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 Jamila Mwidau, Regulatory Project Manager, at (301) 796-4989.

Sincerely,

{See appended electronic signature page}

Anthony J. Murgo, M.D.
Acting Deputy Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

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

/s/

ANTHONY J MURGO
05/03/2011