CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022534Orig1s000

OTHER ACTION LETTERS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022534 **TENTATIVE APPROVAL**

Salamandra, LLC
Attention: Karin A. Kook, Ph.D.
US agent for Sun Pharma Global FZE
4800 Hampden Lane, Suite 900
Bethesda, MD 20814

Dear Dr. Kook:

Please refer to your new drug application 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 submission(s) dated May 4, 2009, May 14, 2009, July 10, 2009, July 20, 2009, August 20, 2009, August 21, 2009, August 26, 2009, September 3, 2009, December 28, 2009, January 4, 2010, January 7, 2010, February 2, 2010, February 12, 2010, February 20, 2010, February 21, 2010 and February 23, 2010.

This NDA provides for the use of DOCEFREZ™ (docetaxel) for Injection, 20 mg/vial and 80 mg/vial for breast cancer, non-small cell lung cancer, prostate cancer, and gastric adenocarcinoma.

We completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed upon labeling (package insert submitted on February 23, 2010, patient package insert submitted on February 23, 2010, immediate container and carton labels submitted on February 23, 2010). This determination is contingent upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of any new information that may come to our attention.

The listed reference drug product upon which you based your application is subject to a period of patent protection and therefore final approval of your application under section 505(c)(3) of the Act (21 U.S.C. 355(c)(3)) may not be made effective until the period has expired, i.e., November 22, 2013.

At least 50 days prior to November 22, 2013 or when requested, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Failure to submit this amendment will prompt a review of the application that may result in rescission of the tentative approval letter.

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 inserts 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

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

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 indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable and the disease/condition does not exist in children.

If you have any questions, call Alberta Davis-Warren, Regulatory Project Manager, at (301) 796- 3908.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: Package Insert, Patient Package Insert, Carton and Container Labels

40 Page(s) of Draft Labeling has been Withheld in Full as B4 (CCI/TS) immediately following this page

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22534	ORIG-1	SUN PHARMA GLOBAL FZE	DOCEFREZ INJECTION (20/80 MG/VIAL)

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

02/23/2010

Anthony J. Murgo, M.D., M.S. signing for:
Robert L. Justice, M.D., M.S.