DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021938/S-031

SUPPLEMENT APPROVAL

C.P. Pharmaceuticals International
Attention: Brian F. Caselli, MSc
445 Eastern Point Rd.
MS-8260-1118
Groton, CT 06340

Dear Mr. Caselli:

Please refer to your Supplemental New Drug Application (sNDA) dated May 22, 0215, received May 22, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sutent® (sunitinib malate).

This Changes Being Effected supplemental new drug application provides for container labels specific for professional samples of Sutent® (sunitinib malate) 12.5 and 25 mg Capsules.

APPROVAL & LABELING

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

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the carton and immediate-container labels submitted on May 22, 2015, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 021938/S-031**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Jeannette O'Donnell, Regulatory Project Manager, at (240) 402-4978 or email Jeannette.Odonnell@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Geoffrey Kim, MD
Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

GEOFFREY S KIM
11/16/2015