



ANDA 201275

Mylan Pharmaceuticals Inc.
Attention: Joseph J. Sobecki
Vice President, Regulatory Affairs
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) received on January 26, 2010, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Sunitinib Malate Capsules, 12.5 mg (base), 25 mg (base), 37.5 mg (base), and 50 mg (base).

Reference is also made to the complete response letter issued by this office on May 24, 2013, and to your amendments dated November 6, and November 27, 2013. We also acknowledge receipt of your communications dated June 21, 2013; and January 3 and January 24, 2014, addressing patent issues associated with this ANDA.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Sunitinib Malate Capsules, 12.5 mg (base), 25 mg (base), 37.5 mg (base), and 50 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Sutent Capsules, 12.5 mg (base), 25 mg (base), 37.5 mg (base) and 50 mg (base), respectively, of CP Pharmaceuticals International CV (CPPI).

The RLD upon which you have based your ANDA, CPPI's Sutent Capsules, is subject to periods of patent protection. The following patents are currently listed in the agency's

publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
6,573,293 (the '293 patent)	February 15, 2021
7,125,905 (the '905 patent)	February 15, 2021
7,211,600 (the '600 patent)	December 22, 2020

With respect to the '293 and '905 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Sunitinib Malate Capsules, 12.5 mg (base), 25 mg (base), 37.5 mg (base), and 50 mg (base), under this ANDA. You have notified the agency that Mylan Pharmaceuticals Inc. (Mylan) complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of these patents was brought against Mylan within the statutory 45-day period in the United States District Court for the District of Delaware [Pfizer Inc. et.al. vs. Mylan Inc. and Mylan Pharmaceuticals, Civil Action No. 10-528-GMS]. You have further notified the agency that the litigation remains pending. Pursuant to sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the Act, the 7½-year period during which your ANDA could not be approved, has expired.

With respect to the '600 patent your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that this is a method of use patent that does not claim any indication for which you are seeking approval under your ANDA.

With respect to that part of the '293 patent pertaining to a method of use (b)(4), your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that you are not seeking approval under your ANDA for (b)(4) insofar as it pertains to (b)(4)

With respect to 180-day generic drug exclusivity, we note that Mylan was the first ANDA applicant for Sunitinib Malate Capsules, 12.5 mg (base), 25 mg (base), 37.5 mg (base), and 50 mg (base), to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Mylan may be eligible for 180 days of generic drug exclusivity for Sunitinib Malate Capsules, 12.5 mg (base), 25 mg (base), 37.5 mg (base), and 50 mg (base). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing

identified in section 505(j) (5) (B) (iv). The agency notes that Mylan failed to obtain tentative approval of this ANDA within 40¹ months after the date on which the ANDA was filed. See section 505(j) (5) (D) (i) (IV) (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Mylan's eligibility for 180-day generic drug exclusivity. It will do so only if a subsequent paragraph IV applicant becomes eligible for full approval (a) within 180 days after Mylan begins commercial marketing of Sunitinib Malate Capsules, 12.5 mg (base), 25 mg (base), 37.5 mg (base), and 50 mg (base), or (b) at any time prior to the expiration of the last listed patent if Mylan has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert 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

¹ For applications submitted between January 9, 2010 and July 9, 2012, section 1133 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (P.L. 112-114) extended the 30-month period to 40 months.

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dose forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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

/s/

ROBERT L WEST

01/30/2014

Deputy Director, Office of Generic Drugs, for
Kathleen Uhl, M.D.