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*APPLICATION NUMBER:*

**203085Orig1s000**

**MEDICAL REVIEW(S)**

## CLINICAL REVIEW

Application Type NDA  
Application Number(s) 203085  
Priority or Standard Priority

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Division / Office Division of Oncology Products  
2 / Office of Hematology  
Oncology Products

Reviewer Name(s) Shan Pradhan, MD  
Kaushik Shastri, MD  
Review Completion Date September 5, 2012

Established Name Regorafenib  
Trade Name Stivarga  
Therapeutic Class Multikinase inhibitor  
Applicant Bayer Health Care  
Pharmaceuticals, Inc.

Formulation(s) 40 mg oral tablet  
Dosing Regimen 160 mg (four 40 mg tablets)  
taken orally once daily for 21  
days of a 28-day cycle  
Indication(s) Treatment of patients with  
metastatic colorectal cancer

who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy

Intended Population(s) Adults  $\geq$  18 years of age

Template Version: March 6, 2009

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