CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-465

REMS

NDA 022465 VOTRIENT™ (pazopanib) TABLETS

Drug Class and Formulation: Multi- tyrosine Kinase Inhibitor

Glaxo Wellcome Manufacturing Pte Ltd d/b/a GlaxoSmithKline

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of this REMS is to inform patients about the serious risks associated with the use of VOTRIENT (pazopanib).

II. REMS ELEMENTS

A. Medication Guide

GlaxoSmithKline will ensure that a Medication Guide is available for distribution to patients with each VOTRIENT (pazopanib) prescription in accordance with 21 CFR 208.24.

GlaxoSmithKline will include a statement *"Dispense the Medication Guide, attached or provided separately, to each patient pursuant to Federal law"* on the label of each container or package of VOTRIENT (pazopanib) instructing the authorized dispenser to provide a copy of the Medication Guide each time a prescription of VOTRIENT (pazopanib) is dispensed.

B. Communication Plan

A Communication Plan is not required for approval of this REMS.

C. Elements To Assure Safe Use

Elements to Assure Safe Use are not required for approval of this REMS.

D. Implementation System

Because this REMS does not include Elements to Assure Safe Use, an Implementation System is not required for approval of this REMS.

E. Timetable for Submission of Assessments

GlaxoSmithKline will submit REMS Assessments to FDA 18 months, three years, and seven years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. GlaxoSmithKline will submit each assessment so it will be received by the FDA on or before the due date.