Risk Evaluation and Mitigation Strategy
REMS

NDA 22-165 CAMBIA®
Nonsteroidal Anti-Inflammatory Drug (NSAID**)**

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I. GOALS

To inform patients about the serious risks associated with the use of CAMBIA, particularly the increased risk of cardiovascular events and gastrointestinal toxicity.

II. REMS ELEMENTS
A. Medication Guide

CAMBIA is packaged to be dispensed as a single unit package and is not intended to be subdivided prior to dispensing. The Medication Guide is included as part of the secondary package. One Medication Guide will be dispensed with each CAMBIA prescription. Pursuant to 21 CRF 208.24(d) appropriate wording will be placed on the outer cartons of the medication to remind the dispenser to provide the patient with the Medication Guide.

B. Communication Plan

The REMS for CAMBIA does not include a communication plan.

C. Elements to Assure Safe Use

The REMS for CAMBIA does not include elements to assure safe use.

D. Implementation System

Because the REMS for CAMBIA does not include elements to assure safe
Use an implementation system is not required for this product.

III. Timetable for Submission of Assessments

Assessment of the REMS will be performed as follows:
Assessment Protocol* Submission to FDA: On or before the end of October 2010,
1st FDAAA assessment: On or before the end of December 2010,
2nd FDAAA assessment: On or before the end of June 2012,
3rd FDAAA assessment: On or before the end of June 2016.
Kowa will submit the final assessment reports within 60 days from the close of the above projected assessment periods.

*The Assessment Protocol submission will include methodology and instruments to be used to evaluate the patients' understanding about the safe use of CAMBIA. This will include, but not be limited to:

- Sample size and confidence associated with that sample size
- How the sample will be determined (selection criteria)
- The expected number of patients to be surveyed
- How the participants will be recruited
- How and how often the surveys will be administered
- Explain controls used to minimize bias
- Explain controls used to compensate for the limitations associated with the methodology
- The survey instruments (questionnaires and/or moderator's guide).
- Any background information on testing survey questions and correlation to the messages in the Medication Guide.