CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-202

REMS

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to communicate the key safety information on Zipsor™ (diclofenac potassium) Liquid Filled Capsules.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each Zipsor prescription.

Pursuant to 21 CFR 208.24, the Medication Guide will be made available in sufficient numbers to US Zipsor™ distributors. Trade Packages will be packaged as follows: six (6) 100-count bottles in a bundle with a PI on each bottle and a pad of 24 Medication Guides in the bundle. Eight (8) bundles will be packaged in a corrugated shipper (48 total bottles per shipper/192 Medication Guides per shipper).US distributors will provide the Medication Guide with every pharmacy shelf container of Zipsor™ to ensure its availability for dispensing to patients who are dispensed Zipsor™. The label of each container or package of Zipsor™ will include a prominent instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed.

In addition, the Medication Guide will be included with all samples and trade packets intended for direct distribution to patients.

B. Timetable for Submission of Assessments

The assessment interval period will close no earlier than 60 days prior to the date the respective assessment is due as noted below:

- 1st Assessment: 18 months after NDA approval
- 2nd Assessment: 3 years after NDA approval
- 3rd Assessment: 7 years after NDA approval

The assessments will include an evaluation of the effectiveness of the Medication Guide in communicating the risks of Zipsor.