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**ANDA #72-744 - Metoclopramide Oral Solution**

**Gastrointestinal Agent**

**Pharmaceutical Associates, Inc.**

**201 Delaware Street**

**Greenville, SC 29605**

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**PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOALS**

The goal of this REMS is to minimize the risk of tardive dyskinesia associated with the long-term use of Metoclopramide Oral Solution.

**II. REMS ELEMENTS**

**A. Medication Guide**

Pharmaceutical Associates, Inc. will package extended content labeling containing four (4) copies of the Medication Guide and an extra copy of the Medication Guide attached to the approved Package Insert (R05/09) with each 16 oz bottle of Metoclopramide Oral Solution USP, 5 mg/5mL. This will permit the pharmacist to distribute a copy of the Medication Guide to each patient receiving the dispensed prescription. The bottle label will inform the pharmacist to dispense the Medication Guide.

Pharmaceutical Associates, Inc. also packages Metoclopramide Oral Solution, 5 mg/5mL unit dose cups. Our unit dose cups are packaged with ten (10) cups in a shrink-wrapped tray. The labeling on the unit dose cups states "INTENDED FOR INSTITUTIONAL IN-PATIENT DISPENSING. IF OTHERWISE DISPENSED, AN APPROPRIATE CHILD-RESISTANT CONTAINER SHOULD BE USED". Since this product is intended for use in a hospital or other health care setting, we are proposing to attach one (1) medication guide to each tray label, which will be on top of the unit dose cups shrink-wrapped tray.

The Medication guide is appended to the REMS.

**B. Communication Plan**

The REMS for ANDA # 72-744 - Metoclopramide Oral Solution does not include a Communication Plan.

**C. Elements To Assure Safe Use**

The REMS for ANDA #72-744 - Metoclopramide Oral Solution does not include an Elements to Assure Safe Use.

**D. Implementation System**

The REMS for ANDA #72-744 - Metoclopramide Oral Solution does not include an Elements to Assure Safe Use and as such, an Implementation System is not required.

**E. Timetable for Submission of Assessments**

The REMS for ANDA #72-744 - Metoclopramide Oral Solution does not include a Timetable for Submission of Assessments.