RISK EVALUATION AND MITIGATION STRATEGY (REMS)

1. GOALS

The goal of this REMS is to communicate the key safety information on TRADENAME™ (tapentadol) in order to reduce the risks of serious adverse events, inappropriate use, and inappropriate storage and disposal.

2. REMS ELEMENTS

2.1. Medication Guide

Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI), will include a supply of package inserts that include the Medication Guides to the wholesaler with each shipment of TRADENAME™ (tapentadol) in accordance with 21 CFR 208.24.

OMJPI will separately supply additional copies of the pre-printed Medication Guides to all retail and hospital pharmacies to ensure that every patient who is dispensed a prescription will have access to the TRADENAME™ (tapentadol) Medication Guide. These additional shipments will occur at least biannually.

2.2. Communication Plan

The REMS for TRADENAME™ (tapentadol) does not include a Communication Plan.

2.3. Elements to Assure Safe Use

The REMS for TRADENAME™ (tapentadol) does not include Elements to Assure Safe Use.

2.4. Implementation System

The REMS for TRADENAME™ (tapentadol) does not include Elements to Assure Safe Use, therefore, an implementation system is not required.

2.5. Timetable for Submission of Assessments

REMS Assessments will be submitted to FDA in accordance with the following schedule:

Assessment Submission	Date	Timing Relative to Approval
1st Assessment	Day Mon Year	18 months after approval
2nd Assessment	Day Mon Year	3 years after approval
3rd Assessment	Day Mon Year	7 years after approval