

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**125290**

**REMS**

Appendix A: Proposed REMS

**Extavia (Interferon beta-1b)**

**Novartis Pharmaceuticals Corporation  
One Health Plaza  
East Hanover, NJ 07936-1080**

**Proposed 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 Extavia.

**II. REMS ELEMENTS**

**A. Medication Guide**

A Medication Guide will be dispensed with each Extavia prescription. In accordance with 21 CFR 208.24, Novartis will package one Medication Guide per carton. Extavia is supplied in blister units (15 per carton). Extavia is packaged as a single unit of use. Based on the assumption that from one prescription a pharmacist will dispense a single carton of 15 blister units, one copy of the Package Insert together with the Medication Guide will be included in every carton by the sponsor at the time of manufacture/packaging. This will ensure the Medication Guides are available for distribution to each patient. The carton of Extavia will state how the medication guide is provided: *"Dispense the enclosed Medication Guide to each patient."* This will appear on the carton to inform the pharmacist to dispense with Medication Guide.

**B. Timetable for Submission of Assessments**

Novartis Pharmaceuticals Corporation will submit the REMS assessments to the FDA according to the following timetable of assessments:

1st assessment:	February 28, 2011 (18 months after approval)
2nd assessment:	August 31, 2012 (3rd year after approval)
3rd assessment :	August 31, 2016 (7th year after approval)

The assessment period will close no earlier than 60 days prior to the date the respective assessment is due. The assessment is to be received by the FDA on the due date.