# BL103964/5147 Pegasys (peginterferon alfa-2a)

# Proposed Risk Evaluation and Mitigation Strategy (REMS):

## I. GOAL

Inform patients about the serious risks associated with the use of PEGASYS, including risks to pregnancy, mental health problems, blood problems, liver problems, infections, eye problems, and stroke.

## II. REMS ELEMENTS:

### A. Medication Guide

The proposed REMS for Pegasys consists of the FDA approved Pegasys Medication Guide. As part of the standard packaging configuration for Pegasys, a Medication Guide is included in each package of Pegasys, and thus, is automatically provided to the patient with each prescription.

## III. REMS ASSESSMENTS:

### A. Timetable for Assessments

A REMS assessment will be submitted to FDA no less frequently than at 18 months, 3 years and 7 years after FDA approval the initial Pegasys REMS on October 31, 2008 with the specific submission dates of:

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|---|---|---|
| 1st REMS assessment: | April 30, 2010 | (18 months from approval) |
| 2nd REMS assessment: | October 31, 2011 | (3 years from approval) |
| 3rd REMS assessment: | October 31, 2015 | (7 years from approval) |

### B. Information Needed for Assessments

a) Survey of patients' understanding of the serious risks of Pegasys

**Roche Proposal:** A proposed protocol for a Mediation Guide survey is included in this submission for FDA review and will be updated to include eye problems upon FDA approval of the final Medication Guide wording for eye problems.

b) Because the Medication Guide is packaged with the product, issues concerning distribution and dispensing of the Medication Guide are not applicable.