

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
201152Orig1s000

REMS

Initial REMS Approval: 06/2008
Most Recent Modification: 03/2011

Appendix A: Proposed REMS Modification

NDA 20-636 VIRAMUNE (nevirapine) Tablets
NDA 20-933 VIRAMUNE (nevirapine) Oral Suspension
NDA 201-152 VIRAMUNE (nevirapine) Extended-Release Tablets

Non-nucleoside reverse transcriptase inhibitor (NNRTI) with activity against Human Immunodeficiency Virus Type 1.

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S):

The goal of this REMS is to inform patients about the serious risks associated with the use of VIRAMUNE (nevirapine).

II. REMS ELEMENTS:

A. Medication Guide

Boehringer Ingelheim Pharmaceuticals Inc. will ensure that Medication Guides are available for distribution to patients in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

Boehringer Ingelheim Pharmaceuticals will submit REMS Assessments to the FDA at a minimum, by 18 months, by 3 years, by 4 years and by 7 years from the date of approval of the initial REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Boehringer Ingelheim Pharmaceuticals will submit each assessment so that it will be received by the FDA on or before the due date.