NDA 21-254___ ADVAIR HFA ((salmeterol and fluticasone propionate)**)**

PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to communicate the risks of ADVAIR HFA.

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each ADVAIR HFA prescription. ADVAIR HFA is packaged as a single unit of use. The Medication Guide is inserted inside the carton prior to insertion of the overwrapped MDI unit. Each Medication Guide is barcode scanned to ensure that the correct version is being used and that the component is available for insertion into each carton.

Because the medication guide is included as part of the secondary package for ADVAIR HFA, GSK have met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide.

B. Communication Plan

The REMS for ADVAIR HFA does not include a Communication Plan.

C. Elements To Assure Safe Use

This REMS for ADVAIR HFA does not include elements to assure safe use.

D. Implementation System

Because this REMS for ADVAIR HFA does not include elements to assure safe use, an implementation system is not required.

III. Assessment of REMS

The Timetable for Assessments is as follows:

1st FDAAA assessment: January 2010 (18 months from approval)
2nd FDAAA assessment: July 2011 (3 years from approval)
3rd FDAAA assessment: July 2015 (7 years from approval)

GSK will submit the assessments within 60 days of the close of the intervals as noted above.