RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Single, Shared System for Rosiglitazone-Containing Medicines

I. GOAL

The goal of the Rosiglitazone REMS Program for the rosiglitazone-containing medicines (hereafter referred to as rosiglitazone) is to provide training to likely prescribers of rosiglitazone medicines about the current state of knowledge concerning the cardiovascular risks of these medicines.

II. REMS ELEMENTS

A. Elements to Assure Safe Use

1. Training will be provided to healthcare providers who are likely to prescribe rosiglitazone medicines of the current state of knowledge on the medicines’ cardiovascular risk.

   a. Rosiglitazone REMS Sponsors will ensure healthcare providers who are likely to prescribe rosiglitazone are provided training, for the duration of the REMS. Training materials on the current state of knowledge concerning the cardiovascular risk of these medicines will be available on the Rosiglitazone REMS website (www.rosiglitazonerems.com).

   The following materials are part of the REMS and are appended:
   - training slide deck

   In order to facilitate prescriber training

   b. A Dear Healthcare Provider Letter (DHCP letter) will be distributed via direct mail within 14 working days of the approval of the REMS Modification (May 2014). The target audience for this communication will be likely prescribers, defined as prescribers who had written a prescription for rosiglitazone one year prior to the implementation of the original restricted distribution of the REMS program in June 2011. In addition, this letter will be sent by electronic mail to those prescribers currently enrolled in the REMS program.

   Rosiglitazone REMS Sponsors will send the Dear Healthcare Provider Letter to MedWatch prior to the time the letter is disseminated to the target audience.

   c. A Dear Professional Society Letter will be distributed to the leadership of the following societies via direct mail or electronic mail within 14 working days of the approval of the REMS Modification (May 2014):

      - American Association of Clinical Endocrinologists (AACE)
d. The Rosiglitazone REMS Sponsors will make the following materials available on a REMS website (www.rosiglitazonerems.com) for the duration of the REMS following approval of this REMS modification:

1. Prescriber training materials (the training slide deck)

2. Dear Healthcare Provider Letter

3. Prescribing Information and Medication Guides for all rosiglitazone-containing medicines (branded and generic versions) that are approved

4. Contact information for the manufacturers of approved rosiglitazone-containing medicines

The Dear Healthcare Provider Letter, Dear Professional Society Letter, and REMS website are part of the REMS and are appended.

Based on monitoring and evaluation of these elements to assure safe use, Rosiglitazone REMS Sponsors will take reasonable steps to improve implementation of these elements and to maintain compliance with the Rosiglitazone REMS Program requirements, as applicable.

D. Timetable for Submission of Assessments

Rosiglitazone NDA Sponsor(s) will submit REMS assessments to FDA 6 months, 12 months, and annually from the date of initial approval of this REMS with ETASU (May 18, 2011). 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. Rosiglitazone NDA Sponsor(s) will submit each assessment so that it will be received by the FDA on or before the due date.