

## **Qsymia<sup>®</sup> Risk Evaluation and Mitigation Strategy (REMS)**

### **Pharmacy Enrollment Form - Mail Order Pharmacy**

Because of the teratogenic risk associated with Qsymia therapy, Qsymia is available through a limited program under the REMS. Under the Qsymia REMS, only certified pharmacies may distribute Qsymia. I understand that my certified mail order pharmacy must comply with the program requirements for certified pharmacies and the terms contained in this form. As the Authorized Pharmacy Representative, I acknowledge that:

1. I have reviewed and successfully completed the Qsymia Pharmacy Training Program and the knowledge assessment questions.
2. I understand the risks associated with Qsymia.
3. I understand and agree to comply with the requirements of the Qsymia REMS program for pharmacies.
  - a. The pharmacy management system is in place, and has been validated, to systematically direct that a Medication Guide and the *Risk of Birth Defects with Qsymia* patient brochure be provided to each patient each time Qsymia is dispensed.
  - b. The pharmacy will refrain from reselling or transferring Qsymia to another pharmacy or distributor.
  - c. The pharmacists and staff involved with the dispensing of Qsymia will be trained before dispensing Qsymia about the risks associated with Qsymia and the REMS requirement to provide a Medication Guide and the *Risk of Birth Defects with Qsymia* patient brochure each time Qsymia is dispensed.
  - d. The pharmacy and pharmacy personnel will cooperate with pharmacy audit requirements in order to maintain pharmacy certification.
  - e. The pharmacy will maintain a list of Qsymia prescribers that will be provided to VIVUS monthly.
4. I will oversee compliance with the Qsymia REMS program requirements and will provide quarterly compliance reports back to VIVUS to assess effectiveness and comply with all audit requirements.



**Authorized Pharmacy Representative to complete (all fields required):**

**First Name** \_\_\_\_\_ **Last Name** \_\_\_\_\_

**Phone Number** \_\_\_\_\_ **Fax** \_\_\_\_\_

**Email** \_\_\_\_\_

**Mail Order Pharmacy Name** \_\_\_\_\_

**Address** \_\_\_\_\_ **City** \_\_\_\_\_

**State** \_\_\_\_\_ **Zip Code** \_\_\_\_\_

**Signature** \_\_\_\_\_ **Date** \_\_\_\_\_

**Authorized Pharmacy Representative**

**Please fax this completed form to the Qsymia REMS Pharmacy Support Center at 1-855-302-6699.**

**If you have any questions or require additional information, please contact the Qsymia REMS Pharmacy Support Center at 1-855-302-6698.**

