RISK EVALUATION AND MITIGATION STRATEGY (REMS)

GOAL

The goal of the Xeljanz REMS is to mitigate the risk of serious infections, malignancies, lymphoproliferative disorders, increased cholesterol, and low blood cell counts associated with Xeljanz by:

• Informing healthcare prescribers and pharmacists about the above risks.

REMS ELEMENTS:

Communication Plan

Pfizer Inc will implement a communication plan to the following healthcare providers:

• Rheumatologists and rheumatology healthcare providers (including physician assistants and nurse practitioners) who are likely to prescribe XELJANZ,

• Infectious disease specialists who may be consulted about and treat serious infections including herpes zoster, tuberculosis, and other opportunistic infections,

• Family practitioners, general practitioners, and internal medicine specialists who may be consulted about and be involved in treating serious infections, decreases in neutrophil counts, decrease in lymphocyte counts, decreases in hemoglobin, and lipid elevations and hyperlipidemia,
Elements of the communication plan include the following:

1. A Dear Healthcare Provider Letter will be distributed twice annually for 2 years from the date of initial approval (11/2012) and once within 60 days of the date of the modification approval (6/2015) to rheumatologists and rheumatology healthcare providers (including physician assistants and nurse practitioners), infectious disease specialists, family practitioners, general practitioners, internal medicine specialists, and emergency medicine specialists through both traditional mailing and electronic mailing. The initial letter will be distributed within 60 days of product approval. The Dear Healthcare Provider Letter is enclosed in Appendix A.

The Prescribing Information and a copy of the Medication Guide will also be distributed in this communication.

2. A Dear Pharmacist Letter will be distributed twice annually for 2 years from the date of initial approval (11/2012) and once within 60 days of the date of the modification approval (6/2015) through both traditional mailing and electronic mailing. The initial letter will be distributed within 60 days of product approval. The Dear Pharmacist Letter is enclosed in Appendix B.

3. Dissemination of information about the known and potential serious risks associated with XELJANZ will be made to healthcare providers through certain professional societies’ scientific meetings and journals.

   o Display, for 2 years following product approval, as a panel/poster and distribution as printed material at major convention meetings of rheumatologists and other healthcare professionals specializing in rheumatology where the company has a sponsored booth (e.g., American College of Rheumatology, Congress of Clinical Rheumatology, and American Society of Health System Pharmacists annual meetings).

   o Quarterly, for 3 years following product approval, presentation as a printed information piece in The Rheumatologist, Arthritis & Rheumatology, Arthritis Care & Research, Clinical Infectious Diseases, Annals of Emergency Medicine, American Family Physician, Annals of Internal Medicine, American Journal of Health-System Pharmacy, and Journal of the Academy of Managed Care Pharmacy. The drafts of the important drug warning that will be printed in the aforementioned scientific journals are enclosed in Appendices C through Appendix G.

4. Pfizer will ensure that all materials listed in or appended to the XELJANZ REMS program will be available through the XELJANZ REMS program website.
The XELJANZ REMS program website will exist for 3 years following approval of the REMS. The landing page for the XELJANZ REMS website is appended (see Appendix H).

**Timetable for Submission of Assessments**

Pfizer will submit REMS Assessments to the FDA at 18 months, by 3 years and 7 years from the date of approval of the REMS (11-06-2012). 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. Pfizer will submit each assessment so that it will be received by the FDA on or before the due date.