Initial REMS Approval: 04/2010

Most Recent Modification: 07/2011

# HUMIRA® (ADALIMUMAB)

# BLA 125057

Abbott Laboratories

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# RISK EVALUATION AND MITIGATION STRATEGY (REMS)

## I. GOAL

To communicate and mitigate the risks associated with HUMIRA® therapy by:

- Alerting and warning healthcare providers about unrecognized histoplasmosis and other invasive fungal infections associated with Tumor Necrosis Factor (TNF) blocker use.

## II. REMS ELEMENTS

### A. Communication Plan

In accordance to FDCA 505-1(e)(3), Abbott will implement a communication plan to healthcare professionals (HCPs) who prescribe TNF blockers including gastroenterologists, rheumatologists (adult and pediatric), and other specialists (e.g. internal medicine, emergency medicine, pediatricians, infectious disease, and family medicine) who may potentially prescribe TNF blockers, by conveying the following information:

- The risk of developing invasive fungal infections, including histoplasmosis, coccidioidomycosis, blastomycosis, and other opportunistic fungal infections while treating with TNF blockers.
- Descriptive information on the signs and symptoms of fungal infections, including histoplasmosis, as well as references and background information regarding the treatment of these infections.

This element of the REMS is not intended to continue over the lifetime of the product; it will function only to disseminate the new safety information about histoplasmosis and other invasive fungal infections associated with TNF blocker use.

The communication plan includes a *Dear Healthcare Provider Letter* and the *Invasive Fungal Infection Awareness Education Brochure.*

1. Dear Healthcare Provider Letter

The Dear Healthcare Professional Letter will be distributed to inform HCPs of an important expanded safety update about HUMIRA® and the potential risk of under-recognition of histoplasmosis and other invasive fungal infections. The Letter will be distributed by mass mailing to the HCPs in the following specialties at a minimum: rheumatologists (adult and pediatric), gastroenterologists, dermatologists, internal medicine physicians, family medicine physicians, emergency medicine physicians, pediatricians, and infectious disease specialists. In the Dear Healthcare Provider Letter, HCPs will be instructed to share the information with any outpatient clinical staff involved in teaching patients self-injection techniques for the administration of HUMIRA®. The Dear Healthcare Professional Letter will also be available for download and printing at the www.humirarems.com website, which may be accessed from product websites (www.humira.com and www.myhumira.com).

Please see the appended Dear Healthcare Provider Letter.

2. The Invasive Fungal Infection Awareness Education Brochure

The Invasive Fungal Infection Awareness Educational Brochure will describe the potential risk of under-recognition of histoplasmosis and other invasive fungal infections associated with the use of HUMIRA®.

The target audience for the Invasive Fungal Infection Awareness Educational Brochure will be the same as for the Dear Healthcare Professional Letter. The Invasive Fungal Infection Awareness Educational Brochure will be distributed in the same mailing as the Dear Healthcare Provider letter. The Invasive Fungal Infection Awareness Educational Brochure will also be available for download and printing at the www.humirarems.com website, which may be accessed from product websites (www.humira.com and www.myhumira.com). Finally, the Invasive Fungal Infection Awareness Educational Brochure will be made available upon inquiry from Abbott Medical Information at the following US medical professional meetings (American Academy of Dermatology [AAD], Digestive Disease Week [DDW], American College of Gastroenterology [ACG], and American College of Rheumatology [ACR]).

**B. Timetable for Assessment of the REMS**

Abbott will submit REMS Assessments to FDA 18 months, 3 years and 7 years from the date (April 8, 2010) of the initial approval of the 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. Abbott will submit each assessment so that it will be received by the FDA on or before the due date.