Adverse Event Intake Form

PATIENT INITIALS OR IDENTIFIER: _____

Call: 1-888-908-8796
Fax: 1-609-301-6230

☐ **Initial**

☐ **Follow Up**

Instructions:
- *Enter time as military time.*
- *Complete form in black ink and in English.*
- *Indicate estimated dates/times with asterisk(*).*
- *Required fields are in boldface text.*
- *Write "NA" in lines that are not applicable.*
- *Call SAEs to 1-888-908-8796 upon notification.*
- *Fax completed forms to 1-609-301-6230.*
- *Enter dates using the day, first 3 letters of the month, then the year (dd-mmm-yyyy). Ex: May 12, 2015 to be entered as 12-MAY-2015*

1. PATIENT INFORMATION

Patient Name:

Patient Address:

City, State, ZIP:

Phone: | Email:

Age at Time of Event or Birthdate:

Weight: _____lbs. | Height: _____ ft. _____ in. | **Sex:** ☐ **Male** ☐ **Female**

Ethnic Origin: ☐ Caucasian ☐ Asian ☐ Black/African American ☐ Other: _____

2. ADVERSE EVENT INFORMATION

Type of AE: ☐ **Non-serious adverse event** ☐ **SERIOUS ADVERSE EVENT**

If Serious Adverse Event, check seriousness criteria reported to Company Agent (check all that apply):

☐ **Life-threatening** ☐ **Congenital Anomaly / Birth Defect** ☐ **Disability or Permanent Damage**

☐ **Hospitalization (initial or prolonged)** ☐ **Fatal (date of death):** _____

☐ **Other Serious (Important Medical Condition):** _____

Date / Time of Onset of Event: _ _ - _ _ _ - _ _ _ _ (d d - m m m - y y y y) _____ military time | Time from dosage to event: ___hrs. ___mins.

Date / Time Event Stopped: _ _ - _ _ _ - _ _ _ _ (d d - m m m - y y y y) _____ military time or ☐ Continuing

Event Name and Description:

List any Relevant Tests or Laboratory Data, including Dates. If death, include autopsy date and results:

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3. PATIENT OUTCOME (at time of report)

Has patient recovered from event? ☐ **Recovered** ☐ **Recovering** ☐ **Recovered with Sequelae** ☐ **Not Recovered** ☐ **Fatal** ☐ **Unknown**

Treatment of Event (if drugs, include drug names, dosage, frequency, and start and stop dates):

Was the drug stopped, delayed, or reduced in response to the event? ☐ **No:** *Move on to section 4–Suspect Product*

☐ **Yes:**

Action	Details	Did the event abate after drug stopped/delayed/reduced?
☐ **Drug Stopped**	**Date / Time Stopped:** _ _ - _ _ _ - _ _ _ _ _____ (dd - mmm - yyyy military time)	☐ **Yes** ☐ **No**
☐ **Dosage Delayed**	**Specify number of dosages delayed:**	☐ **Yes** ☐ **No**
☐ **Dosage Reduced**	**New dose:** **Route:** **Site:** **Frequency:**	☐ **Yes** ☐ **No**

NOTE: If an additional event appeared after reintroduction, complete another AE Intake Form.

4. SUSPECT PRODUCT

Drug Name:	**Labeled Strength:**	**Lot #:**	**Exp:**

Patient Prescribed **Dose:** **Frequency:**
Route: **Site:**

Patient Diagnosis / Indication For Use:

Start Date of *Current* Prescription/Therapy: _ _ - _ _ _ - _ _ _ _ (dd - mmm - yyyy)

Has the patient been prescribed this drug *prior* to the Current Prescription?

☐ **No:** *Move on to Section 5–Patient Medical History*

☐ **Yes:** Dates of Previous Therapy: # of Therapies:

Dose: Frequency: Route: Site:

Previous Reaction:

5. PATIENT MEDICAL HISTORY

Relevant medical history / diagnoses, including preexisting conditions (e.g. – pregnancy, allergies, surgeries, smoking and alcohol use, hepatic / renal dysfunction, etc.)

ACTIVE	INACTIVE

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Concomitant Medical Products and Therapy Dates (Exclude medical products used for treatment of adverse event)

Drug Name, Dose, Frequency, Indication	**Start Date**	**Stop Date or "C" if Continuing**

6. INITIAL REPORTER (IF NOT PATIENT)

Name:	**Phone:**
Email:	
Address:	**City / State / ZIP:**
Health Professional? ☐ **No** ☐ **Yes – Occupation:**	

7. PRESCRIBER CONTACT INFORMATION

Name:	
Phone :	Fax:
Email:	
Address:	City / State / ZIP:

8. COMPANY AGENT COMPLETING FORM

☐ **USWM CoC Nurse Network** ☐ **Other:** _____

Your Name:

Phone:	**Email:**
Date you were notified of Adverse Event: _ _ - _ _ _ - _ _ _ _ (d d - m m m - y y y y)	**Today's Date:** _ _ - _ _ _ - _ _ _ _ (d d - m m m - y y y y)

I have spoken to the Prescriber: ☐ No ☐ Yes:
- Was additional information obtained? ☐ No ☐ Yes – Complete another AE Intake Form
- Prescribers opinion of drug relationship as reported to company agent: ☐ Related ☐ Unrelated

To your knowledge, have any regulatory authorities been informed of the Adverse Event?
☐ **No** ☐ **Yes – Details:**