Date received:

SUSPECT DRUG INFORMATION:

Product: _____

Indication for use: _____

Dosage: _____

Route: _____ Lot #: _____ Expiry Date: _____

Start Date (dd/mmm/yyyy): _____ Stop Date (dd/mmm/yyyy): _____

Other (duration): _____ Therapy ended? ☐Yes ☐No ☐Unknown

REPORTER INFORMATION:

☐Physician (MD) Specialty: _____ ☐ Dentist (DDS/DMD) ☐Pharmacist ☐ Nurse

☐Sales Rep ☐Consumer ☐Other: _____

Name: First_____ Last name: _____

Address: _____

_____

Phone: _____ Fax:_____

E-mail:_____

PATIENT INFORMATION**:**

Sex: ☐Male ☐Female ☐Unknown Patient Initials: _____

Date of Birth (dd/mmm/yyyy):_____ Age: ____ Weight: _____ ☐lbs ☐kg

Pregnant: ☐Yes ☐No ☐Unknown If yes, due date (dd/mmm/yyyy):_____

SERIOUS OUTCOME CRITERIA:

Death	☐ Yes	☐No	☐Unknown
Life-Threatening	☐ Yes	☐No	☐Unknown
Hospitalization (required or prolonged)	☐ Yes	☐No	☐ Unknown (Dates:)
Disability/Incapacity	☐ Yes	☐No	☐Unknown
Congenital anomaly	☐ Yes	☐ No	☐Unknown
Other medically significant condition	☐ Yes	☐No	☐Unknown (Specify:)

ADVERSE EVENT INFORMATION:

Event Details:

Start Date: _____ Stop Date: _____

Suspect drug withdrawn? ☐ Yes ☐ No ☐ Unknown

Suspected drug dose reduced? ☐ Yes ☐ No ☐ Unknown

If yes did the event improve? ☐ Yes ☐ No ☐ Unknown

Suspected drug reintroduced? ☐ Yes ☐ No ☐ Unknown

If yes did the event reoccur? ☐ Yes ☐ No ☐ Unknown

RELEVANT MEDICAL HISTORY: (Including pre-existing medical/surgical conditions)

Current Conditions: (Specify dates, if known)

Prior conditions: (Specify dates, if known)

Allergies: Yes (Specify:) ☐ None ☐ Unknown

CONCOMITANT MEDICATIONS: (Includes prescription, OTC and herbal/natural products)

Generic/Trade Name	**Indication**	**Dose/Route/Frequency**	**Start Date (dd/mmm/yyyy)**	**Stop Date (dd/mmm/yyyy)**

ADVERSE EVENT INFORMATION: (Include relevant tests/laboratory data and any treatment patient received, diagnosis made)

(Attach additional sheet if necessary)

CONSENT TO CONTACT HEALTHCARE PROFESSIONAL (HCP): ☐ Yes ☐ No

CALLER GAVE CONSENT TO PASS DETAILS TO PHARMACOVIGILANCE: ☐ Yes ☐ No

(If yes, name of individual providing consent and date):

_____

Name of individual obtaining consent:

_____

Details of HCP: Name: _____ Profession: _____

Contact details: (Address/telephone number/fax/email):

_____