Please complete the following sections for the case identified above.
Patient and reporter information will be kept confidential.

CASE DEFINITION FOR ADVERSE DRUG REACTIONS – SERIOUS AND LIFE-THREATENING

Serious and life-threatening adverse drug reactions (ADRs)* in an infant or child 18 years or less, associated with the use of prescription, non-prescription, biological (immunoglobulins) products, complementary medicines (including herbals), and radiopharmaceutical products.

Report even if you are not certain if the product caused the adverse reaction or you do not have all the reporting details.

Exclusions: Do not report reactions due to medical devices, blood products (platelets, red cells, single donor plasma), vaccines, poisonings or self-administered overdoses.

* Noxious and unintended severe response to a drug which occurs at any dose and results in emergency observation, hospitalization, persistent or significant disability, or death.

SECTION 1 – PATIENT INFORMATION

1.1 Date of birth: ____ / ____ / ________

1.2 Height: ________ inches or ________ cm

1.3 Weight: ________ lbs or ________ kg

1.4 Country of family ancestry

Mother: _______________ Father: _______________

1.5 Race: _______________

1.6 Sex: Male ___ Female ___

SECTION 2 – ADVERSE REACTION

2.1 Describe reaction (including site of reaction):

_________________________________________________________________________________________________

2.2 Date of reaction: ____ / ____ / ________

2.3 Causality of ADR – The drug was the: possible cause ___ or probable cause ___ or definite cause ___

SECTION 3 – SUSPECTED DRUG PRODUCT(S)

3.1 Name (give labeled strength and manufacturer, if known)

3.2 Dose, frequency and route used

Dose _____ Frequency __________

Route used: Oral__ IV__ IM__ SC__ Other__

3.3 Therapy dates (if unknown, give duration)

From ____ / ____ / ________ to ____ / ____ / ________

Duration _________________________________

3.4 Indication for use of suspected drug product:

_________________________________________________________________________________________________