A. Patient Information

Patient Name: .....

Age: ..... Date of Birth *(e.g. 01-Jan-1900)*: .....

Sex:

☐ Male ☐ Female

Weight: ..... ☐ lb ☐ kg

Race and/or Ethnicity *(select all that apply)*:

☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Hispanic or Latino
☐ Middle Eastern or North African
☐ Native Hawaiian or Pacific Islander
☐ White

B. Adverse Event, Product Problem

Type of Report *(select all that apply)*:

☐ Adverse event
☐ Product use/medication error
☐ Product problem *(e.g. defects/ malfunctions)*
☐ Problem with different manufactuer of same medicine

Outcome Attributed to Adverse Event *(select all that apply)*:

☐ Death - Date of death: .....
☐ Hospitalization *(initial or prolonged)*
☐ Lift-threatening
☐ Disability or Permanent damage
☐ Required intervention to prevent permanent impairment/damage
☐ Congenital anomaly/birth defects
☐ Other serious or importamtn medical events

Date of Event *(e.g. 01-Jan-1900)*: .....

Date of this report *(e.g. 01-Jan-1900)*: .....

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Describe Event, Problem or Product Use/Medication Error *(characters max 4,000)*:

Relevant Test/ Laboratory Data	Low Test Range	High Test Range	Date

Additional Comments *(characters max 2,000)*:

Other Relevant History, Including Preexisting Medical Conditions
(e.g. allergies, pregnancy, tobacco product use, liver/kidney problems etc.)
(characters max 2,000):

C. Product Availability

Product available for evaluation?

☐ Yes ☐ No

☐ Returnerd to Manufacturer on *(e.g. 01-Jan-1900)*: .....

Do you have a picture of the product? While not required, pictures of all sides of the product will help to review your report. *(check yes if including pictures)*:

☐ Yes

D. Suspect Products

SUSPECT PRODUCT #1

Name, Strength, Manufacturer/Compounder *(from product label)*:

Product Name: ..... Strength: .....

Unit: Millitre(s) NDC # or Unique ID: ..... Lot #: .....

Manufacturer Name: .....

Place and Date of Purchase:

Name: .....

Address: .....

City: ..... State/Province/Region: .....

ZIP/Postal Code: ..... Country: .....

Website *(if purchased online)*: ..... Purchase Date: .....

Dose or Amount: ..... Frequency: .....

Route: ..... Unit: .....

Treatment/Therapy/Usage Dates *(give best estimate of length of treatment/usage (start/stop) or date of dose reduction):*

Therapy/Usage started on *(e.g. 01-Jan-1900)*: .....

Therapy/Usage stopped on *(e.g. 01-Jan-1900)*: .....

Dose reduced on *(e.g. 01-Jan-1900)*: .....

Is therapy/usage still on-going?

☐ Yes ☐ No

Diagnosis for use *(Indication)*:

Product Type *(select all that apply)*:

Drug or Biologic

- ☐ Brand
- ☐ Generic or Biosimilar
- ☐ Over-the-counter (OTC)
- ☐ Compounded product
  (by a pharmacy or an outsourcing facility)

Cosmetics *(select one):*

- ☐ Cosmetics for Professional use only
- ☐ Cosmetics sold on a retail basis

Other product types

- ☐ Cannabinoid hemp products
  (such products containing CBD)
- ☐ Other

Expiration Date *(e.g. 01-Jan-1900)*: .....

Event Abated after use stopped of dose reduced?

☐ Yes ☐ No ☐ Doesn't apply

Event reappeared after reintroduction

☐ Yes ☐ No ☐ Doesn't apply

SUSPECT PRODUCT #2

Name, Strength, Manufacturer/Compounder *(from product label)*:

Product Name: ..... Strength: .....

Unit: Millitre(s) NDC # or Unique ID: ..... Lot #: .....

Manufacturer Name: .....

Place and Date of Purchase:

Name: .....

Address: .....

City: ..... State/Province/Region: .....

ZIP/Postal Code: ..... Country: .....

Website *(if purchased online)*: ..... Purchase Date: .....

Dose or Amount: ..... Frequency: .....

Route: ..... Unit: .....

Treatment/Therapy/Usage Dates *(give best estimate of length of treatment/usage (start/stop) or date of dose reduction):*

Therapy/Usage started on *(e.g. 01-Jan-1900)*: .....

Therapy/Usage stopped on *(e.g. 01-Jan-1900)*: .....

Dose reduced on *(e.g. 01-Jan-1900)*: .....

Is therapy/usage still on-going?

☐ Yes ☐ No

Diagnosis for use *(Indication)*:

Product Type *(select all that apply)*:

Drug or Biologic

- ☐ Brand
- ☐ Generic or Biosimilar
- ☐ Over-the-counter (OTC)
- ☐ Compounded product
  (by a pharmacy or an outsourcing facility)

Cosmetics *(select one):*

- ☐ Cosmetics for Professional use only
- ☐ Cosmetics sold on a retail basis

Other product types

- ☐ Cannabinoid hemp products
  (such products containing CBD)
- ☐ Other

Expiration Date *(e.g. 01-Jan-1900)*: .....

Event Abated after use stopped of dose reduced?

☐ Yes ☐ No ☐ Doesn't apply

Event reappeared after reintroduction

☐ Yes ☐ No ☐ Doesn't apply

E. Reporter

Name and Address:

Last Name: ..... First Name: .....

Address: .....

City: ..... State/Province/Region: .....

ZIP/Postal Code: ..... Country: .....

Phone #: ..... Email: .....

Health Professional? Occupation: .....

☐ Yes ☐ No

Also Reported to:

☐ Manufactuer/Compounder

☐ User Facility

☐ Distributor/Importer

☐ Packer