

Adverse Event Record

Date Report Received: _____

Report Received By: Mail Email Phone Text Other: _____

Reporting Person

Name: _____

Address: _____

Phone: _____

Email: _____

Adverse Event Details

Note briefly; file any applicable documents or details.

Product Details

Name: _____

Batch #: _____ Date Made: _____

Purchase Date: _____

Where Purchased: _____

Other Details: _____

Report(s) Submitted to FDA

Save & file copies of all reports made.

Report Date: _____ By: Mail Online Portal

Report Date: _____ By: Mail Online Portal

Report Date: _____ By: Mail Online Portal

Report Date: _____ By: Mail Online Portal

Additional Data Received About Adverse Event

Other Relevant Data

Directions

Log pertinent summary information on this form. Keep copies of all correspondence, reports, and documentation in a comprehensive file. Records must be kept for 6 years (3 years for a small business). Allow an FDA Inspector access to all related records.