

COLITASGOLD STANDARD OPERATING PROCEDURE

Title: Product Recall and Withdrawal Procedure

Product: CPCO - Complex Phytocannabinoid Cannabis Oil

Document Number: CG-RC-001 **Version:** 1.0 **Brand:** ColitasGold

1. PURPOSE AND SCOPE

This procedure provides a rapid, controlled and documented process for withdrawing or recalling ColitasGold CPCO where a quality, safety, manufacturing, packaging, labelling or regulatory concern is identified. It applies throughout the distribution chain, including ColitasGold, Afriplex (Pty) Ltd, distributors, wholesalers, veterinary practices and retailers.

2. WHEN A RECALL MAY BE INITIATED

A recall may follow contamination; incorrect formulation or concentration; raw-material, manufacturing or stability failure; defective packaging or labelling; batch-identification or container-integrity problems; significant or recurring adverse events; animal-safety concerns; regulatory instruction; or another material quality or safety concern.

3. RESPONSIBILITIES AND INITIAL ACTION

ColitasGold coordinates any withdrawal or recall and appoints a Recall Coordinator. Afriplex (Pty) Ltd, as contract manufacturer, provides manufacturing and batch information and investigates relevant quality concerns. Distributors maintain distribution records and comply promptly with recall instructions. ColitasGold assesses the concern, affected batch(es), quantity and distribution, remaining stock and related reports. Distribution may be suspended and stock quarantined pending investigation.

4. RECALL DECISION, TRACEABILITY AND NOTIFICATION

Senior management decides whether to recall or withdraw product, consulting Afriplex and appropriate advisers where necessary. Relevant South African regulatory authorities shall be notified where required. Batch records must permit traceability of quantities received, distributed and remaining. Recall notices shall identify the product and batch, explain the reason, instruct recipients to stop sale or distribution and quarantine stock, and provide return or collection instructions.

5. RECOVERY, INVESTIGATION AND CLOSURE

Returned product shall be segregated and quantities reconciled. Where manufacturing or quality is implicated, Afriplex shall conduct or participate in a documented investigation. Corrective action may include testing, process or packaging changes, supplier review, training, communication or suspension of manufacture/distribution. Recalled stock remains quarantined until formally returned, retained for investigation or destroyed. Recall effectiveness and closure shall be documented and records retained.

Approved by: Dr Roy Aronson **Position:** CEO ColitasGold PTY Ltd

Signature: _____ **Date:** _____

COLITASGOLD

STANDARD OPERATING PROCEDURE

Title: Pharmacovigilance and Adverse Event Reporting Procedure
Product: CPCO - Complex Phytocannabinoid Cannabis Oil
Document Number: CG-PV-001 **Version:** 1.0 **Brand:** ColitasGold

1. PURPOSE AND SCOPE

This procedure establishes a formal process for receiving, recording, assessing, investigating and following up suspected adverse events associated with ColitasGold CPCO. Reports may come from veterinarians, veterinary personnel, distributors, retailers, pet owners, the manufacturer or others involved with the product, whether or not they believe CPCO caused the event.

2. ADVERSE EVENTS AND RESPONSIBILITIES

An adverse event is any undesirable, unexpected or concerning clinical occurrence following administration of CPCO; reporting does not establish causation. Serious events include death, life-threatening conditions, significant or persistent disability, prolonged hospitalisation or veterinary treatment, or other medically significant events. ColitasGold maintains an Adverse Event Register and designates a Safety Officer or Responsible Person. Afriplex shall be notified where an event may relate to product quality, formulation, contamination, stability, manufacture or a specific batch.

3. INFORMATION TO RECORD

Where available, record reporter and veterinarian details; animal signalment and relevant history; CPCO batch/lot, start date, dose, frequency and reason for use; event description and timing; concurrent medicines or supplements; veterinary treatment; response after discontinuation; any independently occurring re-administration; and outcome. A report shall not be rejected because some information is unavailable.

4. ASSESSMENT AND INVESTIGATION

Each report receives a unique reference number and is entered in the Adverse Event Register. Assessment considers timing, dose and duration, underlying disease, concurrent products, previous exposure, response to discontinuation, foreseeable ingredient effects, possible overdose or administration error, similar reports and batch patterns. ColitasGold shall not instruct re-administration solely to test whether an event recurs.

5. SERIOUS EVENTS, SAFETY SIGNALS AND CORRECTIVE ACTION

Serious or recurring events and batch clusters receive priority and are escalated to senior management. Appropriate veterinary, scientific, regulatory and legal advice shall be obtained where necessary, and relevant South African regulatory authorities notified where required. Potentially affected batches may be quarantined and investigated with Afriplex. The register shall be reviewed for safety trends. Corrective action may include testing, manufacturing or raw-material review, changes to storage, instructions or warnings, communication, temporary suspension, withdrawal or recall.

6. CONFIDENTIALITY, RECORDS AND REVIEW

Personal information shall be handled confidentially in accordance with applicable South African data-protection requirements. Reports, investigations, correspondence and corrective actions shall be securely retained. This procedure shall be reviewed periodically and after significant safety events, recalls or material regulatory changes.

Approved by: Dr Roy Aronson **Position:** CEO ColitasGold PTY Ltd

Signature: _____ **Date:** _____