TO ALL APPLICANTS

APPLICATION TO CONDUCT A CLINICAL TRIAL

The following are the requirements when submitting a clinical trial application.

1. Covering letter.
2. Cover sheet.
3. Checklist.
4. Completed Application form.
5. All documents to be submitted in duplicate with two electronic copies.
6. Additional 25 copies of the application form itself must be submitted.
7. Protocol
8. Patient Information leaflet and Informed consent form
9. Standardized MCC contact details/wording to be added to PILs.
10. Investigators Brochure/Package insert.
11. Signed investigator(s) CV(s) in MCC CVs format.
12. Signed Declaration by Principal investigator(s).
13. Signed joint declaration by Sponsor/National Principal investigator.
14. Signed Provisional declaration by Co- or Sub-investigators
15. Signed Declaration by regional monitor
16. Indemnity and Insurance Certificate and/or
17. Proof of Malpractice insurance of trialist(s).
18. Ethics committee(s) approval or
19. Copy of letter submitted to Ethics committee(s).
20. Diskettes to be submitted in word.
21. Financial declaration

SOUTH AFRICA : CLINICAL TRIAL APPLICATION

SECTION 1 – CHECK-LIST OF REQUIRED DOCUMENTATION

To be completed by Applicants for all Clinical Trials

COVER SHEET

Study Title:

Protocol No:

Version No: **Date of Protocol:**

Study Drug:

MCC Ref number (if applicable):

MCC Ref number(s) of comparator drug(s) (if applicable):

MCC Ref number(s) of concomitant drug(s) (if applicable):

Date(s) MCC approval of previous protocol(s):

Sponsor:

Applicant:

Contact Person:
Address:
Telephone Number: **Fax Number:**
Cell Number:
E-mail address:

To be completed by MCC

Date original application received:

Tracking No:

Proposed Clinical Trials Committee Meeting Date if applicable:

Signature: **Date:**

ACKNOWLEDGEMENT OF RECEIPT OF CTA (Contact details to be completed by the applicant). Whole cover sheet to be faxed to applicant once details in block above are completed.

Contact Details: Name : **Fax No.:**

Receipt of new application is hereby acknowledged. **Date:**

Signature (of MCC recipient): **Name:**

CHECKLIST

Applicant's check list		MCC double-check
☐	COVERING LETTER	☐
☐	FULLY COMPLETED APPLICATION (SECTIONS 1–3)	☐
☐	PROTOCOL (INCLUDING RELEVANT QUESTIONNAIRES ETC.)	☐
☐	PATIENT INFORMATION LEAFLET(S) AND INFORMED CONSENT(S)	☐
☐	INVESTIGATORS BROCHURE AND / OR ALL PACKAGE INSERT(s)	☐
☐	INVESTIGATOR'S CV(s) IN MCC FORMAT	☐
☐	SIGNED DECLARATION(s) BY INVESTIGATOR(s)	☐
☐	REGIONAL MONITOR'S CV AND DECLARATION	☐
☐	CERTIFICATE(S) OF ANALYSIS (May be submitted with ethics approval letter)	☐
☐	INSURANCE CERTIFICATE	☐
AND IF NECESSARY:		
☐	LETTER ENDORSING GENERIC INSURANCE CERTIFICATE	☐
☐	ETHICS APPROVAL	☐
OR		
☐	COPY OF LETTER APPLYING FOR ETHICS COMMITTEE APPROVAL	
☐	COPY/IES OF RECRUITMENT ADVERTISMENT(s) (IF APPLICABLE)	☐
☐	FINANCIAL DECLARATION (SPONSOR AND NATIONAL PI)	☐

Electronic versions of the application form (Sections 1 –3), the protocol, the investigator's brochure and/or other relevant documents:

☐ LABELLED DISKETTE/CD-ROM (MSWORD OR RICH TEXT FORMAT) ☐

List of files submitted on diskette/CD-ROM:

NB: DO NOT SUBMIT THE APPLICATION IF DOCUMENTATION IS INCOMPLETE: IT WILL NOT BE PROCESSED

Declaration by applicant:

We, the undersigned have submitted all requested and required documentation, and have disclosed all information which may influence the approval of this application.

We, the undersigned, agree to ensure that if the above-said clinical trial is approved, it will be conducted according to the submitted protocol and South African legal, ethical and regulatory requirements.

Applicant (local contact)	Date
National Principal Investigator / National Co-ordinator / Other (state designation)	Date

SECTION 2 – ADMINISTRATIVE AND SUPPLEMENTARY DETAILS

Title:

Protocol Number/identification:

Date of protocol (initial/final):

Part 1: CONTACT DETAILS (NAME/ADDRESS/TEL/CELL/FAX/E-MAIL)

1.1 Applicant: (as in Section 1)

1.2 Sponsor: (as in Section 1)

1.3 If no sponsor – person or organisation initiating, managing, and / or funding the clinical trial:

1.4 Local Contact Person for correspondence:

1.5 National Principal Investigator/Coordinator: (or equivalent person)

1.6 International Principal Investigator: (if applicable)

1.7 Regional Monitor: (as in Section 1)

Part 2: DETAILS OF INVESTIGATIONAL PRODUCT(s)

2.1 Name(s) and details of investigational product(s) to be used in trial: [Formulation(s) and strength(s) (e.g. 10 mg/ml–10ml amp.)] Include MCC registration number and date of registration if applicable.

2.2 Name(s) and details (as above) of comparator product(s) and MCC registration number(s) and date(s) of registration if applicable: [Ensure package inserts or complete pharmacological information been included (Section 1).]

2.3 Name(s) and details (as above) of concomitant medication(s) including rescue medications which are required in the protocol, and MCC registration number(s) if applicable: [Ensure package inserts or complete pharmacological information has been included with application (Section 1).]

2.4 Estimated Quantity of Trial Material (each drug detailed separately) for which exemption will be required:

2.5 If any of the above drugs are available in South Africa, give an explanation for not using what is available in South Africa:

2.6 Details of receiving of drugs from supplier, storage, dispensing, packaging of drugs:

2.7 Date MCC registration applied for – or envisaged date of application for trial medication. Explain if registration is **not** envisaged:

2.8 Registration status of entity, for the indication to be tested in this trial, in other countries: (i.e. Country: date registered / date applied for / date registration refused / date registration withdrawn by applicant / date registration cancelled by regulatory authority) [Attach as an appendix if necessary.]

Part 3: DETAILS OF TRIALIST(s) AND SITE(s)

3.1 Details of Investigator(s): [designation, title: (i.e. principal investigators / investigators) Include Name/Address/Tel/Cell/Fax/E-Mail]

3.2 Current work-load of Investigator(s): (Number of studies currently undertaken by trialist(s) as principal and/or co- or sub-investigator, and the total number of patients represented by these studies. Time-commitments of researcher(s) in relation to clinical trial work *and* non-trial work.)

Recommended format for response:

Investigator (Name and designation):			
Total number of current studies (all stages) on specified date	Number	Date	
Total number of patients / participants for which responsible on specified date	Number	Date	
ESTIMATED TIME PER WEEK [168 hours denominator]		**Hours**	**%**
Clinical trials	Clinical work (patient contact)		
	Administrative work		
Organisation (Practice / university / employer)	Clinical work		
	Administrative work		
Teaching	Preparation / evaluation		
	Lectures / tutorials		
Writing up work for publication / presentation			
Reading / sourcing information (e.g. internet searches)			
Other (specify)			

3.3 Details of Site(s) (Name of site, physical address, contact details, contact person, etc.)

3.4 Capacity of Site(s): (Number of staff, names, qualifications, experience -- including study co-ordinators, site facilities, emergency facilities, other relevant infrastructure)

Part 4: PARTICIPANTS (SUBJECTS)

4.1 Number of participants in South Africa:

4.2 Total worldwide:

4.3 Total enrollment in each SA centre: (if competitive enrollment, state minimum and maximum number per site.)

4.4 Volunteer base from which South African participants will be drawn:

4.5 Retrospective data indicating potential of each site to recruit required number of patients within envisaged duration of trial. (SA Guidelines 2000, Item 3.3, p15) [May be attached. Label clearly as 'Section 2 Item 4.5']

Part 5: OTHER DETAILS

5.1 If the trial is to be conducted in SA and not in the host country of the applicant / sponsor, provide an explanation:

5.2 Estimated duration of trial:

5.3 Name other Regulatory Authorities to which applications to do this trial have been submitted, but approval has not yet been granted. Include date(s) of application:

5.4 Name other Regulatory Authorities which have approved this trial, date(s) of approval and number of sites per country:

5.5 If applicable, name other Regulatory Authorities or Ethics Committees which have rejected this trial and give reasons for rejection:

5.6 If applicable, details of and reasons for this trial having been halted at any stage by other Regulatory Authorities:

5.7 Details if this trial is being undertaken in SADC, any other country in Africa, or any country where there is no regulatory control of clinical trials:

5.8 Previous studies using this agent which have been approved by MCC:

MCC approval number:
Study title:
Protocol number:
Date of approval:
National PI / Principal Investigator:
Date(s) Progress report(s):
Date Final report:

5.9 If any substudies are proposed as part of this protocol, indicate whether or not they will also be done in South Africa. If not, please explain.

Part 6: ETHICS

6.1 Ethics Committee responsible for each site, date of approval or date of application:

6.2 Attach copy of response(s) made by, and/or conditions required by ethics committee(s) if available. Ensure that date of EC response is legible.

6.3 State which Good Clinical Practice (GCP) guidelines are being followed. (Particular reference to the South African guidelines required):

6.4 Details of capacity building component of the trial, if any:

6.5 Details of the training of investigators, monitors, study co-ordinators in terms of carrying out this trial and in terms of GCP:

6.6 Detailed safety and monitoring plan for each site: [May be attached. Label as 'Section 2 Item 6.6']

6.7 Details of trial insurance certificate: (e.g. title, protocol, dates, policy #, amount)

6.8 Details of possible conflict of interest of any person(s)/organisation(s) who/which will be involved in the trial:

6.9 Remuneration to be received in SA Rands: (Investigators) (Trial participants) (Others) Indicate broad breakdown of costs to be covered by this amount – if applicable. [Note: the CTC recommends a minimum compensation of R50.00 per visit for participants travel and incidental expenses.]

Reviewer's comments on Section 2:

SECTION 3 – APPLICANT'S REPORT / PRESENTATION
[Please use Black 12 point Arial Font, using MSWord or rich text format (rtf) for electronic version]

1. Title:

CTC Reviewer's comment:

2. Protocol Number/identification:

3. Rationale for study summarised: (Why should this trial be done at all?) Include statement about South African contribution, if any, to the development of this protocol.

CTC Reviewer's comment:

4. Background information (**summarised** – **essential** points that apply to this trial) [1-2 sentences max for each point]:
Disease / problem
South African context (e.g. local epidemiology)
Properties of Drug / Entity; hypotheses about mechanism of action, etc.
Pre-clinical findings: (e.g. laboratory / animal / toxicity / mutagenicity)
Clinical findings (e.g. phases; PK; PD; dose-finding; ADRs, NNT/NNH, other)
Systematic review(s) and/or citations per year-group on a Medline search

CTC Reviewer's comment:

5. Objectives of study (clearly listed and justified)

CTC Reviewer's comment:

6. Study design (clearly described and each component justified)
[includes phase, use of placebo, dosages, randomisation, blinding, duration, etc.]

CTC Reviewer's comment:

7. Participants: (number of participants; ability to enroll required number within stated time)

CTC Reviewer's comment:

8. Eligibility and enrollment: (Inclusion and exclusion criteria listed and justified)

CTC Reviewer's comment:

9. Treatment modalities and regimens, drug accountability [clearly explained and justified for all participant groups/arms e.g. in terms of route of administration, dose, etc. Drug accountability clearly described.]

CTC Reviewer's comment:

10. Outcome measurements/variables (each clearly stated and justified)

CTC Reviewer's comment:

11. Adverse events (prevention, definitions – including causality assignment, recording, reporting, time-lines, action to be taken, all clearly described)

CTC Reviewer's comment:

12. Statistical measures:
Determination of sample size correct, clear and justified (with and/or without stratification)
Statistical method(s) and analysis of quantitative measures appropriate, clear and justified
Statistical method(s) and analysis of qualitative measures appropriate, clear and justified
Data processing (how, where, when, who) clearly described and justified. If a SA person will be involved in data processing, please identify that person
Interim analysis envisaged or not (justify) and stopping rules if applicable (explain)

CTC Reviewer's comment:

13. Ethical Issues: justification of 'Section 2 part 6' including:

- Explanation of which GCP guidelines are or are not being followed – with particular reference to the South African guidelines
- Comment on choice of investigators (refer to point C of Introduction, page 2 SA Clinical Trials Guidelines 2000)
- Comment on need for, appropriateness of, and relevance of GCP training / updating / for staff involved in this trial
- Comment on capacity building element of trial
- Comment on resources of sites and sponsor
- Comment on monitors and monitoring plan
- Indicate how additional staff (monitors, pharmacists, nursing staff, etc.) will maintain patient confidentiality, follow the protocol, and abide by ethical and regulatory requirements
- Comment on insurance and indemnity measures
- Comment on Patient Information Leaflet and Informed Consent (NB: inclusion of ABPI guidelines; appropriate level of education/English; possible benefits / risks clear; ensuring patient rights; contact names and numbers, as well as MCC details, included)
- Comment on availability and completeness of separate PILs and informed consent forms for any proposed archiving of blood specimens for later research or for genetics research.
- Comment on ethics of the publication policy
- Comment on treatment and/or management of participants and their disease condition(s) after completion of trial
- Comment on ethics committee capacity to monitor site if not a local ethics committee
- Provide an explanation if minimum recommended compensation for participants is not being provided.

CTC Reviewer's comment:

14. Other relevant information not included above
E.g. Are references adequate and dates of references current?
Are there discrepancies between protocol and IB or package inserts? Are there specific explanation(s) for these discrepancies?
Are the explanations for not following the SA 'GCP guidelines' acceptable?
Other comments on this trial.

CTC Reviewer's comment:

For office use:

CTC Reviewer's questions and concerns to be considered and/or forwarded to applicant:

CTC Reviewer's recommendation:

Declaration of conflict of interests by CTC reviewer:

CTC recommendation (date): 1A, 1B, 2, 3, 4, 5

MCC decision (date):

RECALLS

MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

GUIDELINES FOR RECALL OF MEDICINES

This document has been prepared to serve as a recommendation to applicants regarding the recalls of medicines, and the Medicines Control Council's current thinking on the safety, quality and efficacy of medicines. Council reserves the right to request for any additional information to establish the safety, quality and efficacy of a medicine and may make amendments in keeping with the knowledge which is current at the time of consideration of data which has been submitted regarding any recalls. The MCC is committed to ensure that all medicines that are registered are of the required quality, safety and efficacy. It is important for applicants to adhere to these requirements.

REGISTRAR OF MEDICINES
MS. M.P. MATSOSO
DATE: 29/04/2003

Version 2003MCC/1

INDEX

GUIDELINES FOR RECALL/WITHDRAWAL OF MEDICINES

1. INTRODUCTION

The guidelines for recall/withdrawal of medicines is the result of an agreement between the holder of the certificate of registration/parallel importer of the medicine and the Department of Health: (Medicines Control Council) (MCC) in South Africa. Its purpose is to define the action to be taken by the Cluster: Medicines Regulatory Affairs: Directorate: Inspectorate and Law Enforcement and the holder of the certificate of registration /parallel importer of the medicine, when medicines for reasons relating to their safety, quality and efficacy are to be removed from the market.

The Registrar of Medicines, the Director and Deputy Director: Inspectorate ad Law Enforcement and the Medicines Control Officer(s) are responsible for recall/ withdrawal, and will monitor closely the effectiveness of the holder of the registration certificate/parallel importer's recall actions and provide a scientific, technical and operational advice.

Each holder of a certificate of registration certificate(HCR)/parallel importer should advice the Medicines Regulatory Affairs (MCC) of the names, after hours and telephone numbers of two persons who have authority to discuss and, if necessary, implement a recall.

These guidelines serve to remind the holder of a certificate of registration/parallel importer that the Medicines Control Council expects them to take full responsibility for medicines recalls, including follow-up checks to ensure that the recalls are successful.

Most recalls are conducted on voluntary basis. The MCC can recall medicines when registration thereof has been cancelled, or when medicines are sold illegally in South Africa. If the recalling performance is deemed inadequate the MCC is prepared to take appropriate actions to remove the product from sale or use.

2. DEFINITIONS

Recall-means the removal of a specific batch/batches of a medicinal product from the market for reasons relating to deficiencies in the quality, safety or efficacy.

Withdrawal-means the total withdrawal of a medicinal product from the market

Medicine-means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in-

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man: or
(b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine

Parallel importation- means the importation into the Republic of a medicine protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of such patent holder.

Parallel importer- means a person who parallel imports a medicine into the Republic on authority of a permit issued in terms of regulation 7(3) of the Medicines and Related Substances Control Act, 101 of 1965.

Holder of a certificate of registration-means a person in whose name a registration certificate has been granted and who is responsible for all aspects of the medicine, including quality and safety and compliance with conditions of registration

Stock recovery-means a firm's removal or correction of a product that has been released for sale and has not yet been despatched or has not left the direct control of the holder of a certificate of registration/parallel importer (Refer regulation 43(1) of the Medicines and Related Substances Control Act, Act 101 of 1965)

3. PROVISIONS OF THE ACT

3.1 Section 19 (1) of the Medicines and Related Substances Control Act, Act 101 of 1965, Act 101 of 1965 –*No person shall sell any medicine unless it complies with the prescribed requirements. Any person who contravenes provision of this sub-section shall be guilty of an offence.*

3.2 Regulation 43(1)-Every medicine shall comply with the standards and specifications which were furnished to the Council on the form prescribed by regulation 22 and which have been accepted by the Council with regard to such medicine.

4. NOTIFICATION/INITIATION OF THE RECALL

The recall of a medicine can be initiated as a result of reports referred to the holder of a certificate of registration/parallel importer or Medicines Regulatory Affairs (MRA)(MCC) from various sources, e.g. manufacturers, wholesalers, retail and hospital pharmacists, doctors, etc. A report of an adverse drug reaction to a particular batch(es), product quality deficiency, technical complaints experienced with regard to the printed packaging material, contamination, mislabelling, counterfeit including adulterated medicines.

When initiating a recall the holder of a certificate of registration should take the following aspects into consideration: the extent of public warnings and the successfulness of the recall.

5. INFORMATION REQUIRED FOR THE ASSESSMENT OF A RECALL

Recall information	**Information by the HCR/Parallel importer**	**Comments by MRA(MCC))** *(for official use only)*
Origin of report		
1. Name of person/organisation reporting the problem		
2. Company		
3. Physical address		
4. Telephone number		
5. Facsimile number		
6. E-mail address		
7. Date of report		
8. Name of recipient at the MRA		
Product(medicine) details		
1. Name of product affected		
2. Registration number		
3. Dosage form		
4. Strength		
5. Pack size/type		
6. Batch number and expiry date		
7. Manufacturer/holder of the certificate of registration, address and contact details		
8. Date manufactured		
9. Date released		
10. Total quantity prior to distribution		
11. Quantity released for distribution prior to the recall		
13. Date of distribution		
14. Local distribution (*give full details and quantity)*		
15. Overseas distribution (*give full details and quantity)*		
Nature of defect		
1. Source of problem (e.g. patient/hospital/pharmacy/manufacturer, etc)		
2. Details of problem		
3. Number of complaints received		
4. Name and address of any Medicines Regulatory Affairs notified of the problem		
5. Action taken so far (if any)/ Proposed		

action and its urgency		
6. Type of hazard/health risk and assessment of risk to the user		
7. Proposed recall classification and type		
8. Other relevant information		

The above information could be provided verbally but should be confirmed in writing within **3 working days**

For office use only Decision on next action

6. CLASSIFICATION OF RECALLS

Recalls are classified into both the **class** according to the level of health hazard involved (risk to the patient) and **type** which denotes the depth or extent to which the product should be recalled from the distribution chain, e.g. Class I, Type C recall, etc.

Class I
Class I is for defective/dangerous/potentially life-threatening medicines that predictably or probably could result into serious health risk/adverse events or even death.

Class II
Class II is for medicines that possibly could cause temporary or medically reversible adverse health problem or mistreatment.

Class III
Class III is medicines that are defective and are likely to cause any adverse health reaction or which do not comply with the requirements of Act 101 of 1965 in terms of the requirements of printed packaging material, product specification, labelling, etc.

Type A

A type A recall is designed to reach all suppliers of medicines (all distribution points) i.e. Wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised prescribers and dispensers and individual customers or patients through media release (radio, television, regional and national press).

Action: Recall letter to all distribution points plus media release.

Type B

A type B recall is designed to reach wholesalers throughout the country, directors of hospital services (private as well as state hospitals), retail outlets, doctors, nurses, pharmacists, authorised prescribers and dispensers.

Action: Recall letter to all distribution points.

Type C

A type C recall is designed to reach wholesale level and other distribution points (e.g. pharmacies, doctors, hospitals) this can be achieved by means of a representatives calling on wholesalers and/or retail outlets. If it is known where the product in question had been distributed to, specific telephone calls or recalls letters to arrange for the return of the product could be made.

Action: Specific telephone calls, recall letters to/representatives calling at distribution points if known where the medicines have been distributed.

NOTE: Decisions on the class and type of a recall to be initiated are a matter of the Medicines Control Council and Medicines Regulatory Affairs in consultation with a holder of the registration certificate and shall be based on the evidence and/or expert opinion of the MCC and HCR. In the event of greater urgency e.g. after hours or over weekends, the decision to recall can be initiated by HCR.

7. RECALL LETTER CONTENTS

Recall communication from holder of the registration certificate to the distribution chain should be written in accordance with the following directive:

1. Shall be on the company's letterhead and signed by the Managing Director or any authorised person/responsible pharmacist .
2. The heading should indicate that it is an "Urgent Medicine Recall"
3. Name of product, dosage form, strength, registration number, pack size, batch number(s), expiry date and any other relevant information necessary to allow absolute identification

4. Nature of the defect (be brief to the point)
5. Urgency of the action
6. Reason for the action (reason for recall)
7. Indication of a health risk (this should also state exactly what the product may do if taken, i.e., side effects)
8. Provide specific information on what should be done in respect of the recalled medicine. Method of recovery or product correction, which will be used.
9. Where necessary a follow-up communication shall be sent to those who filed to respond to the initial recall communication.
10. A request to retain the letter in a prominent position for one month in case stock is in transit (*where applicable*).
11. Where recalled stock has been distributed to a limited number of hospitals and the recall letter is not to be sent to all hospitals in the province, the letter should include the following:

    " *If any of the recalled stock could have been transferred from your hospital to another, please let that hospital know or alternatively inform our company so that we can make contact with the hospital supplied from your hospital*".

NB: The recall communication shall not contain any material that can be viewed as promotional in nature.

8. MEDIA RELEASE

In a case of a recall where media release is indicated, the holder of a certificate of registration and the MRA makes the text of the media release jointly. Expert advice may also be required.

The media release should contain sufficient information to describe the product and a clear outline of the problem (without causing unnecessary alarm) and must state the appropriate response by the consumer/client.

A 24-hour access telephone number of the holder of the registration certificate should be given for further information. The media release will be issued by the holder of the registration certificate. In the event that the holder of the registration certificate refuses to do a media release the Medicines Control Council will do the release via the Cluster: Communication of the Department of Health.

9. POST RECALL PROCEDURES

The Medicines Control Council shall be furnished within **30 days** of the recall having been instituted with a final reconciliation report. The report shall contain the following information:

NOTE: An interim report may be requested even before the 30 days have elapsed.

Post recall information	**Information by the HCR /Parallel importer**	**Comments by MRA/MCC** (*for official use only)*
1. Name of product		
2. Registration number		
3. Dosage form		
4. Strength of product		
5. Pack size/type		
6. Batch number and expiry date		
7.Nature of defect		
8. Action taken (taking into account the area of distribution of recalled medicine), if exported confirmation from the Regulatory Authority and the holder of the registration certificate in the country of origin		
9. Urgency of the action taken		
10. Reason for the action		
11. Indication of the health risk and the reported clinical problems		
12. Steps taken to prevent re-occurrence of the problem		
13. Fate of the recalled product (including the decision taken)		
14. The result of the recall-quantity of stock returned, corrected, outstanding, etc		
15. Confirmation that		

customers have received the recall letter		
16. Copies of all recall correspondence including previous correspondences to Council regarding this recall.		

For official use only Comments on the success of the recall.

10. REFERENCES

1. Circular 9/98 from the Medicines Control Council.
2. Uniform Recall Procedure for the Therapeutic Goods.

11. CONTACT DETAILS

1. Ms J. Gouws
Director: Inspectorate and Law Enforcement Directorate
Tel: 012 312 0230/47
Fax: 012 312 3114

2. Mr. .K Mofokeng
Deputy Director: Inspectorate and Law Enforcement Directorate
Tel: 012 312 0259
Fax: 012 312 3114

3. Ms H. Moropyane
Principal Medicines Control Officer
Tel: 012 312 0243
Fax: 012 312 3114

4. Ms P. Matsoso
Registrar of Medicines
Tel: 012 312 0285
Fax: 012 312 3105

12. UPDATE HISTORY

Date	Reason for update	Version
April 2003	New	2003/1

CTF 2

MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

APPLICATION FOR PROTOCOL AMENDMENT

Version MCC/2003/1

MCC CLINICAL TRIALS SECTION TRACKING NUMBER FOR THIS CORRESPONDENCE:

REGISTRAR OF MEDICINES
APPLICATION FOR APPROVAL OF:

☐ **PROTOCOL AMENDMENT**
☐ **INCREASE IN NUMBER OF PATIENTS PARTICIPATING**
☐ **CHANGES IN DOSE / REGIMENT OF STUDY DRUG**

Protocol number, title and date

1. APPLICANT

1.1 Name/address/tel/fax number of Applicant wishing to conduct trial

1.2 Name/address/tel/fax number of CRO representing sponsor as Applicant or Local Sponsor Company details (if applicable)

1.3 Name, designation and qualifications of person representing the Applicant (***Local Contact Person for all further correspondence***)

1.4 National Coordinator name, address, tel/fax number

1.5 International Principal Investigator name, address, tel/fax number

1.6 Name of sponsor

2. TRIAL PARTICULARS (original application)

2.1 MCC Approval Number:

2.2 Date of Approval of original protocol:

2.3 Number of Investigators in South Africa already approved for this trial:

2.4 Number of sites in South Africa already approved for this trial:

2.5 Number of patients in South Africa already approved for this trial:

3. AMENDMENT PARTICULARS

(Please list requests for approval)

Does the applicant wish to increase the number of patients participating in this trial in South Africa?

Yes ☐
No ☐

If "Yes" please submit a letter requesting amendment together with this application?

Does the applicant wish to change the dose / regimen of the study drug?

Yes ☐
No ☐

If "Yes" please submit a letter requesting amendment together with this application?

Does this amendment request require a new consent form from the participant?

Yes ☐
No ☐

If "Yes" please submit new PIL together with this application.

3.1 Amendment Number:

3.2 Version Number and Date of Amendment (for each document submitted):

3.3 General motivation for the proposed Amendment: List all the issues included in the amendment and give a rationale for each point being changed)

3.4 Details of the proposed Amendment. For each point or section give a brief motivation and clearly **highlight changes**; this can be done either as **"old text"** replaced with **"new text"** or with the **old text deleted** with a line through it and the **new text in Bold and underlined**:

3.5 Brief description and purpose of the trial (do not repeat title) and motivation for amendment:

3.6 Will this Amendment apply to all approved South African investigators/sites:

YES ☐ **NO** ☐

If NO: Specify the South African investigator(s) / site(s) for which the Amendment will apply:

4. ETHICS COMMITTEE APPROVAL