agriculture

Department:
Agriculture
REPUBLIC OF SOUTH AFRICA

SUBMISSION DOCUMENT REQUIREMENTS, FOR THE REGISTRATION OF STOCK REMEDIES UNDER FERTILIZERS, FARM FEEDS, AGRICULTURAL REMEDIES AND STOCK REMEDIES ACT, 1947 (ACT 36 OF 1947)

Registrar: Act 36/1947
Private Bag x343
0001 Pretoria

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1. Introduction

The following is a guideline on how to submit applications**:**

- **What** forms or documents are required and
- **How** they should be filled in (e.g. application form) or structured (e.g. covering letter).
- *These are not data requirements, for these please consult "Data Requirements for the Registration of Stock Remedies under Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947)"*

Applicants are encouraged to read through this guideline very carefully to avoid disappointment due to incorrect documentation accompanying an application.

The submission of applications only takes place through the Registration Administration section, and appointments must be made prior to the delivery of **any** applications, although postal applications are accepted. (Postal address: Registrar: Act 36/1947, Private Bag x343, 0001, Pretoria)

First-time applicants should please fill out form C, supply necessary documentation (e.g. company registration certificates) and identify a contact person (see E: "Other Applications").

When a prospective Registration Holder of a stock remedy (applicant) applies for the registration (or for an amendment of registration) of a Stock Remedy the following is required:

1. Scientific Data supporting the application (if relevant). See "Data Requirements for the Registration of Stock Remedies under Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947)"
2. Submission documents (these are documents explaining what the applicant is requesting and/or are required to appropriately process the application). These include:
    a. Application Form
    b. Covering letter (if applicable)
    c. Proposed Labels (if applicable)
3. Fees are payable at the prescribed rate and in the prescribed manner. For a full schedule of fees and procedures – please see Fees
4. Applications must be submitted on an individual product basis with individual covering letters per product. Only application types in the B category (refer to table of contents) may be combined per individual product (e.g. Application for Change of shelf life (B8) plus Additional Pack Size (B9) for ABC (G1234))

2. The following are required submission documents for:

A. New Product Registration

1. New Product

Application Form in triplicate (one must have an original signature)
Proposed Labels in triplicate
Covering letter in duplicate (one must have an original signature)
Proof of payment

2. Parallel registration

Application Form in triplicate (one must have an original signature)
Proposed Labels in triplicate
Covering letter in duplicate (one must have an original signature)
Proof of payment
An Affidavit/declaration from the applicant/ registration holder that the parallel product is exactly the same as the mother product except for the name.

3. Daughter registration

Application Form in triplicate (one must have an original signature)
Proposed Labels in triplicate
Covering letter in duplicate (one must have an original signature)
Proof of payment
Authorisation from the registration holder of the Mother product granting permission for the daughter registration.

Note: Daughter and parallel registrations may only be applied for ONCE the mother is registered.

B. Amendments to an existing registration

1. Change of Registration Holder/ Registration Transfer

Covering letter in duplicate (one must have an original signature)
Proof of payment
An Affidavit/declaration from the applicant AND registration holder that the product and label remains exactly the same (save for change in registration holder).
Proposed Label in triplicate.
Authorisation from the Registration holder granting permission for the change in registration holder/ registration transfer.
In the case of a daughter registration, authorisation from the Registration holder of the mother product granting permission for the change in registration holder/ registration transfer of the daughter product is also required.

2. Change of product name

An Affidavit/declaration from the applicant AND registration holder that the product and label remains exactly the same (save for change of name).

Proposed label in triplicate.
Covering letter in duplicate (one must have an original signature)
Proof of payment

3. Change of formulation

Application Form in triplicate (one must have an original signature).
Covering letter in triplicate (one must have an original signature)
Proof of payment

4. Change of/ Additional source of active pharmaceutical ingredient

Application Form in triplicate (one must have an original signature)
Covering letter in duplicate (one must have an original signature)
Proof of payment

5. Change of manufacturing process including Quality Assurance and Control

Covering letter in duplicate (one must have an original signature)
Proof of payment

6. Change of/ Additional Manufacturing Site and/ or Manufacturer

Application Form in triplicate (one must have an original signature)
Covering letter in duplicate (one must have an original signature)
Proof of payment

7. Change of specifications of raw material or final product

Covering letter in duplicate (one must have an original signature)
Proof of payment

8. Change of Shelf-Life of the final product/ Storage conditions/ Additional stability data in support of a (previously submitted or approved) shelf-life

Application Form in triplicate (one must have an original signature)
Covering letter in duplicate (one must have an original signature)
Proof of payment

9. Change of/ Additional Packaging material or pack size of the final product

Application Form in triplicate (one must have an original signature)
Covering letter in duplicate (one must have an original signature)
Proof of payment

10. Change of/ Additional Therapeutic Claim and/or dosage with no change of withdrawal period

Covering letter in duplicate (one must have an original signature)
Proposed Labels in triplicate (please see 3B for a full explanation)
Proof of payment

11. Change of/ Additional Therapeutic Claim and dosage, with change of withdrawal period

Application Form in triplicate (one must have an original signature)
Covering letter in duplicate (one must have an original signature)
Proposed Labels in triplicate (please see 3B for a full explanation)
Proof of payment

12. Change of/ Additional Target Species (with their additional therapeutic claims) **non-**FPA

Covering letter in duplicate (one must have an original signature)
Proposed Labels in triplicate (please see 3B for a full explanation)
Proof of payment

13. Change of/ Additional Target Species (with their additional therapeutic claims) FPA

Application Form in triplicate (one must have an original signature)
Covering letter in duplicate (one must have an original signature)
Proposed Labels in triplicate (please see 3B for a full explanation)
Proof of payment

14. Change of/Additional Withdrawal Period

Application Form in triplicate (one must have an original signature)
Covering letter in duplicate (one must have an original signature)
Proposed Labels in triplicate (please see 3B for a full explanation)
Proof of payment

15. Change of label for ease of use/ better understanding by users/ Change in Safety instructions

Covering letter in duplicate (one must have an original signature)
Proposed Labels in triplicate (please see 3B for a full explanation)
Proof of payment

Note: Please make enquiries if there isn't a description above of the application you wish to submit, prior to submitting.

Note: Scientific data, where relevant in support of the above mentioned applications is required. For more information please see the data requirements.

C. Request for approval of advertisement

Proposed advertisements in triplicate
Covering letter in duplicate (one must have an original signature) please see what is required in the advertisement covering letter below.

Note that each advertisement is seen as a separate application and should therefore have its own covering letter

Note: If trial data is presented in the advertising material, copies of approved protocols and full trial reports are required, even if they have been previously submitted in the dossier.

D. Request for import permit of unregistered product

One covering letter (see below)
Signed trial protocol – see "data requirements"
Proof of payment

E. Other Applications

1. Three-year renewals of Stock Remedy registrations

Covering letter
Proof of payment
Signed declaration that accompanies the renewal notification

Note that Stock Remedy renewal notifications are sent out from 1st April and that the deadline for renewals is 30 June. However, the deadline can be extended by one month by the payment of a penalty. Registrations are considered to be lapsed if renewals do not comply with these deadlines.

2. Change of company details

Covering letter
Form C
Company/ CC Registration Certificate (if applicable)
No fees payable

3. Change of/ Additional company contact person

Authorisation letter on a bona fide letterhead of the Registration Holder, signed by the chief executive/ manager, indicating who the contact persons are, with their ID number(s)
No fees payable

4. Certificate of free sale

Covering letter
Proof of payment

5. Cancellation of registration

Covering letter
Form B
Original Stock Remedy Registration Certificate
No fees payable

6. Certificate of origin

Cover letter (stating the name and Address of the Registration Holder, the Destination and the description of merchandise for example the name of the product and the G-Number)
No fees payable

3. How submission documents must be prepared:

A. The covering letter

The general covering letter:

The covering letter should always be

- typed, not hand written ,
- on a bona fide company letterhead

Date, addressee and addressor:

- be dated as the actual date, or close to the actual date of submission to Registration Administration.
- signed by the designated contact person for the company.
- If the fax number and telephone numbers for the contact person (as on application form) differ from those on the letter head they should appear on the covering letter. i.e. the correct fax number and telephone numbers must appear on the covering letter

The title:
The following should be clearly indicated

- what the submission is for (e.g. re: New Product Registration XYZ),
- in the case of a registered stock remedy the registration number should be quoted (e.g. re: Label amendment for ABC (G 5678))
- the application category letter- number must appear in the title to ensure correct categorization (e.g. Label amendment (B15) for ABC (G 5678)). Refer to the table of Contents for the Categories.

The Body of the letter
The following should be clearly indicated / discussed

- **briefly** describe the reason for the submission if appropriate (e.g To improve the understanding of the user and for better use of language, label amendments are proposed. These do not in any way alter the claims or usage recommendations etc.). In the case of a New Product Registration, this would not be necessary. The reason for submission should not be confused with the Justification for the new product, use etc.
- If the product is a daughter or parallel product this should be clearly stated, and the name and registration number of the mother product should be included.
- the stock remedy must be described (e.g. macrocyclic lactone drench for sheep) if it is a new product registration
- the number of volumes accompanying the submission
- the submission history (excluding renewals) in tabular format, or in a **summarized** manner (in the case of registered products only) e.g:

Submission history for: XYZ		
Date submitted	**Description of submission/ supply of supplementary information**	**Status and Date**
23/01/2005	New product Registration	Registered 20/10/2005
20/01/2006	Advertisement	Approved 4/3/2006
28/4/2006	Extension of Shelf life	Supplementary information required 6/6/2006
25/6/2006	Method of analysis for tests for Extension of Shelf life supplied	Approved 20/7/2006

Note: Supplementary information should be described in detail in the covering letter accompanying supplementary information (e.g. Supplementary information is as follows: Certificate of analysis for cypermethrin and label corrections (pages 4-7)).

The advertisement approval covering letter

The covering letter should always be

- typed, not hand written ,
- on a bona fide company letterhead

Date, addressee and addressor:

- be dated as the actual date or close to the actual date of submission to Registration Administration.
- signed by the designated contact person for the company.
- the correct Fax number and telephone numbers must appear on the covering letter

The title:
The following should be clearly indicated:

- what the submission is for (e.g. re: Request for advertisement approval for XYZ (G 5674)
- Applicants may provide their own unique reference number for each advert to facilitate tracking. (This number must please also appear on the advert itself.)

The Body of the letter
The following should be clearly indicated / discussed

- The type of marketing material submitted – e.g. journal advertisement
- Whether the advert has been approved before
- The name of *every* product advertised in the particular advertisement must be listed with their G number.
- The addition of the table below will greatly facilitate processing of the request:

Product Name	**Reg number (G number)**

Note that each advertisement is seen as a separate application and should therefore have its own covering letter

The import permit request covering letter

Only Import Permits for the importation of unregistered veterinary drugs for purposes of trials for registration are generally accepted. All other requests for import permits for unregistered products (e.g. emergency situation) should be directed to the Registrar's office and if appropriate, the Directorate Veterinary Services.

The covering letter should always be

- typed, not hand written ,
- on a bona fide company letterhead

Date, addressee and addressor:

- be dated as the actual date or close to the actual date of submission to Registration Administration.
- signed by the designated contact person for the company.
- the correct Fax number and telephone numbers must appear on the covering letter

The title:

The following should be clearly indicated

- what the submission is for (e.g. re: Request for import permit for XYZ, prior to performing trial and application for registration),

The Body of the letter

The following should be clearly indicated / discussed

- quantities, including volumes
- name of the product
- and the active ingredient(s), including concentration
- country of origin,
- manufacturer,
- batch number to be imported (if available),
- Technical data sheet or label (in English) containing registration number (of other regulatory body),
- port of entry
- when the product is required
- The letter should clearly state that this is for purposes of trials for registration of stock remedies.
- It should clearly state the registration status of the product elsewhere (i.e. where it is registered)
- The addition of the table below will greatly facilitate processing of the request:

Product	Active	Country of origin	Batch Number	Port of Entry	Manufacturer	Purpose of importation	Volumes

Note that a full trial protocol is required, see data requirements.

NOTE:

In the case of Requests for import permits for products containing ingredients of animal origin or intended for the use in prevention or treatment of controlled diseases, or vaccines, permission also will have to be separately obtained from the Directorate Veterinary Services of the Department of Agriculture

In the case of Requests for import permits for products containing ingredients of plant origin permission also will have to be separately obtained from the Directorate Plant Health of the Department of Agriculture

In the case of Requests for import permits for products containing Genetically Modified Organism(s) (GMO), permission also will have to be separately obtained from Directorate Biosafety of the Department of Agriculture

B. Labels

Note: Label includes carton, package insert and immediate label as per the definition of label in the regulations

Pages of labels must always be sequentially numbered and a footnote or header must appear on each page.

The footnote or header **must** indicate the following: Name of product, G number (if not new product), **date, draft number** and brief description of application (e.g. addition of sheep claims).

Note: The date and draft number will change should corrections be required. The date should please be as close to the date of the covering letter accompanying the corrections, as possible.

Amendments to registrations that require new labels:

Label amendments should be indicated on a currently “approved” label by underlining, with a solid line, any parts that are being added and/or striking through any parts that are to be removed in the proposed label and/or by underlining, with a dotted line, any parts that are

being reworded. Please also supply an amended label in triplicate (with no underlined sections or struck-trough sections).

C. Application form

Application forms should be initialed on each page (excluding last) and dated and signed on the last page. If applicable, the company stamp should also appear on the last page. Please ensure that the application form pages are *sequentially* numbered.

Note that annexures are not acceptable and that the applicable sections of the application form must be comprehensively filled in.

D. How supplementary information should be presented

Corrections of submission documents may be required after an application has been submitted. These will be communicated to the applicant.

If an applicant is required to supply supplementary information or data after the submission of an application, the following is required to accompany the supplementary information/ data

One covering letter
And if required, corrected pages of the application form or label.

The date or header / footer must clearly distinguish supplementary information from the original submission. This is particularly important where supplementary information supersedes the original submission (eg. Shelf-life, Formulation changes, Withdrawal period changes).

Note: If **label** corrections are required, only the corrected pages should be sent. (Make sure that changes on one page do not alter the subsequent pages.)

The authorized signatory must please remember to initial all pages and sign and date the last page of corrected application forms.

4. How to present the submission documentation

The **submission** documentation must **not** be bound (NB: However, *data* and supplementary *data* must always be bound).

Each **complete** document needs to be stapled (e.g. each application form must be stapled, each label must be stapled). Each *series* of documents must be assembled together – either in files, folders or adequately stapled.

In explanation: Documents should be presented as follows from the top:

The covering letter (with original signature)
The application form (with original signature)
The label
Proof of payment

The covering letter
The application form
The label

The application form
The label

5. Fees

For a full outline of the fees procedure and the different fees please consult: fees

6. Progress of submissions

Requests for information regarding the progress of submissions must be directed to Registration Administration in a documented manner.