agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

Directorate: Agriculture Inputs Control, Private Bag X 343, Pretoria, 0001
20 Steve Biko Street, Pretoria
From: The Registrar (Act No 36 of 1947)
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Enquiries: Mr. Jonathan Mudzunga

20 March 2020

All Agricultural Remedy Applicants

Att: All Registration Holders
Regulatory / Technical Managers

RE: ACTIONS TO BE TAKEN BY THE OFFICE OF THE REGISTRAR (ACT NO 36 OF 1947) TO STREAM LINE APPLICATION EVALUATION.

1. The above matter refers.

2. If during an evaluation of an application by the Technical Advisors, any data gaps or shortfalls are identified, the applicant will be notified via e-mail as has been done in the past. Applicants will have 30 calendar days to address and respond to any data gaps or short falls identified for major applications and 7 working days for administrative (minor) applications. Failure to respond to all the questions raised within the specified time will result in the application not being recommended for approval, the applicant will then be informed of the decision and the application will be finalised. It should be noted that if the first response given by the applicant does not correct or does not provide an adequate (scientific) explanation for the data gap or short-fall, the application will not be recommended for approval. The applicant will then be informed of the decision and the application will be concluded.

3. Any data that is added as part of an application that has already been submitted must not have been generated after the date on which the application was submitted. Such data will be disregarded and the evaluation continued. Substitution of a data report is not accepted regardless of when it was generated.

4. Only the service requested in the covering letter and service request forms will be evaluated. If during an evaluation it becomes apparent that an additional service or a change of service is required in order to proceed, it will result in the application not be recommended for approval, the applicant will be informed of the decision and the evaluation concluded.

5. For all service requests relating to already registered products if it is found during the evaluation that there have been any changes made other than those changes listed in the covering letter, the application will automatically not be recommended for approval, the applicant will be informed of the decision and the application finalised.

6. In order to assist with evaluations please can applicants provide the following when request by the Technical Advisors:

   a) For all service requests relating to already registered products, the applicant to provide copies of the latest stamped and approved registration forms and labels of the products.
   b) For parallel registration applications, applicants to provide the approved mother product registration forms and labels.
   c) Where reference labels have been used (e.g. generic, daughter applications), applicants to provide copies of those labels.
   d) For already register sources, applicants to provide the applicable approved registration application forms.

7. For applications that have lapsed "reinstatement" applications, all data sets must be resubmitted as per registration requirements of the original lapsed product. No changes to any other part of the application will be considered. And such changes will result in the application automatically not be recommended for approval, the applicant will be informed of the decision and the application will be finalised.

8. Application forms must be completed fully and comprehensively with all the required information. No referrals to other products are permitted with the exception of daughter and parallel registrations, but this only applies to confidential information.

9. In the case where any new MRL (Maximum Residue Limit) proposals are needed to be done during the evaluation, applicants must confirm if any other MRL has been set in South Africa for that active ingredient. In the case, where no MRL is set/published on any commodity for an active ingredient, full toxicological data will be required as per the Department of Health requirements.

10. In light of the above, on request by the applicant, the applicant will be afforded an opportunity to make necessary changes their applications, which they have already submitted prior to the date of this communication. However, this excludes applications that have been assigned for evaluation by a Technical Advisor or that are under evaluation at the time of such a request is made. Any applications that are revised by applicant must be authorized by the Administration officials in order for them to be returned to their original place in the queue. Applicants must indicate clearly all changes they have made on a new covering letter when re-submitting revised applications.

11. Please feel free to contact the office of the Registrar for further information and advice on the above matter.

Trusting the above is in order.

Yours faithfully,

MR. JONATHAN MALUTA MUDZUNGA
REGISTRAR: Act 36 of 1947