

Enquiries: [Licensing Manager]
Tel: [Telephone Number]
Reference: [Reference]

[Title of Responsible Person]
[Company]
[Address]

Tel: [Responsible Person Telephone Number]
Email: [Email]

Dear Sir/Madam.

RE: PRE-LICENCE STATUS: STATUS OF APPLICATION FOR A LICENCE IN TERMS OF SECTION 22C(1)(b) OF MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965) (THE MEDICINES ACT) AS AMENDED.

The purpose of this letter is to provide the applicant with the status of their application in relation to the various steps leading up to the South African Health Product Regulatory Authority's (SAHPRA's) decision on the licence application in terms of Section 22C(1)(b).

SAHPRA hereby confirms the status of the application submitted by [company] on the [DD MM YYYY] for a licence to manufacture scheduled substances in terms of section 22C(1)(b) of the Medicines Act with the primary permitted activity of cultivation of cannabis for producing scheduled substances i.e cannabidiol or delta-9-tetrahydrocannabinol for medicinal and research use only.

The application is confirmed to have progressed through the following stages to date:

| Stage | Outcome |
|--|---|
| ADMINISTRATIVE SCREENING | |
| Administrative Screening | (Pending / Proceed to Desktop Review / Query) |
| DESKTOP REVIEW | |
| Desktop / Site Master File review | (Pending / Query / Proceed to Site Inspection) |
| SITE INSPECTION | |
| Site inspection conducted | (Pending / In Progress / Report in Progress) |
| Site inspection report sent to the applicant Deadline for Responses to inspection report _____ | (Pending / In Progress / Awaiting Site Responses / Responses Received) |
| Site Inspection Response Review | (Pending / In Progress / Proceed to Licence Recommendation / Verification site inspection required) |
| Verification site inspection conducted | (Not Applicable / Pending / In Progress / Report in Progress) |

| Stage | Outcome |
|---|--|
| Verification site inspection report sent to the applicant Deadline for Responses to inspection report _____ | (Pending / In Progress / Awaiting Site Responses / Responses Received) |
| Verification site inspection Response Review | (Pending / In Progress / Proceed to Licence Recommendation) |
| LICENSING REVIEW | |
| Licensing Unit review of recommendation and licensing requirements | (Pending / In Progress / Decision communicated to Applicant) |

The outcomes outlined above are to be completed within the timelines stipulated by SAHPRA, including responses to reports and addressing of any queries/remedial actions related to Good Agricultural and Collection Practices (GACP) to enable a positive inspection outcome. In the event that the remedial action/s are not satisfactory, the license application will be refused.

This letter does not serve as confirmation of the issuing of a licence. SAHPRA will only issue a licence that permits cultivation of cannabis for medicinal and research purposes upon satisfaction of compliance with relevant regulatory requirements, including GACP, as confirmed by an inspection by SAHPRA. The cultivation and sale of cannabis is prohibited until a licence is issued and all necessary regulatory requirements are met. Manufacture (including cultivation) of scheduled substances without a licence issued in terms of section 22C(1)(b) is a contravention of section 22C(6) of the Medicines Substances Act.

The contents of this letter are based on information available to SAHPRA at the time of its writing and may be verified by contacting the person listed in the Enquiries section above. The information contained in this letter is correct as at the date hereof. SAHPRA maintains the right to amend the content of this letter should any information become available, and/or known, to the Authority.

Yours faithfully

[Name]

MANAGER: LICENSING

Date: