

	BHUTAN FOOD AND DRUG AUTHORITY CERTIFICATION SERVICES		GUIDELINES
	DOC. BFDA-CS-GL-7.2-03	ISSUE 03	REVISION 00 01 MARCH 2023

GUIDELINES FOR CLOSURE OF APPLICATIONS

1. PURPOSE

To provide guidelines while processing of the cases for closure of applications.

2. SCOPE

This Guideline provides information on the Closure of application(s) not maturing for grant of license under the product certification schemes operated by BFDA-CS.

3. RESPONSIBILITIES

3.1 Head, BFDA is responsible for taking a rational decision on the closure of application.

3.2 Certification Manager is responsible for developing the guideline for closure of application and ensuring its implementation.

3.3 Certification Officer is responsible for processing the case for progress/closure of application and follow-up action.

4. GUIDELINES

4.1 The applicant is required to progress the application for product certification at a reasonable speed, demonstrate conformity to relevant Bhutan Standard and offer the operation for audit and drawl of samples for independent testing. Should the applicant fail to do so, the application may be closed.

4.2 Following steps for closure of application may be taken if:

4.2.1 The applicant fails to respond to BFDA-CS's requests for further information following the registration of application (60 days).

4.2.2 The applicant fails to pay the required fees. (60 days). The applicant fails to show readiness for inspection and offer sample for independent testing within 60 days of registration.

4.2.3 Sample drawn during inspection fails in an independent testing

Note-In case more than one sample has been drawn to cover different type/grades of products and more than 50% of such samples fail, it shall be treated as failure of complete sample.

4.2.4 The applicant fails to implement complete corrective actions on discrepancy/variation report after preliminary visit within 30 days of issue of such reports and fails to notify BFDA-CS of any delays. (6 months)

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4.2.5 The applicant fails to carry out corrective actions following evaluation at the agreed times and fails to notify BFDA-CS of any delays. (30 days)

4.2.6. The applicant fails to create testing facilities except when relaxation is given and to have competent technical personnel.

4.2.7 Non-receipt of acceptance of marking fee and STI/set conditions.

4.2.8 The firm has tampered with documents in connection with the grant or operation of the license.

4.2.9 The firm has indulged in corrupt practices or applied external pressures in the context of grant or operation of the license.

4.3 Before rejecting an application, a reasonable opportunity is given to the applicant of being either heard in person or through a representative on his behalf.

4.4 The intention to close the application is sent to the applicant who is given 15 days from receipt of the notice to respond. If no response is received or the response is deemed to be unsatisfactory, the application shall be closed.

4.5 Application fee is not refunded on closure of application.

REFERENCES

BFDA-CS -PR7.4-01 Procedure for Processing of application for certification