

Islamabad, the 2nd September, 2021

NOTIFICATION

F.No.4-2/2017 – DD (H&OTC).- In exercise of the powers conferred by the clause (c) of section 7 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with Rule 3 (2) (d) of the Alternative Medicines & Health Products (Enlistment) Rules, 2014 and in continuation of earlier notification F. No. 8-3/2019-H&OTC dated 26th May, 2021, the Drug Regulatory Authority of Pakistan, is pleased to issue the following guidelines for holder of Drug Manufacturing License, to manufacture the Alternative Medicines and Nutritional Products & Food Supplements, Probiotics under the provisions of the aforesaid rules, namely:-

CHAPTER 1

MANUFACTURE OF ALTERNATIVE MEDICINES (NOT USING CRUDE HERBS), FOOD SUPPLEMENTS AND NUTRITIONAL PRODUCTS, PROBIOTICS.

1. Application of Building Layout Plan:

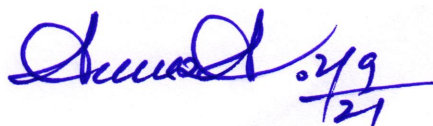
The applicant will apply to the Division of Health & OTC, DRAP for the approval of building lay out. Triplicate copies of existing approved building layout plans, duly marked the section as alternative medicines, Food supplements or nutritional products or Probiotics along with the HVAC drawings (if required), personnel and material flow. The building layout plan will be approved by the said Division as per its SOPs for the approval of building layouts.

2. Application for the grant of enlistment as manufacturer:

The applicant will apply to the Division of Health & OTC on Form-1 along all the annexures as per the checklist posted on the DRAP official website "www.dra.gov.pk" under the Division of Health & OTC including the approved building layout and the fee. The division of Health & OTC will proceed the application as per the approved SOPs for the grant of enlistment as manufacturer (Form-6).

3. Application for the grant of Product enlistment:

The Form-6 holder will apply to the Division of Health & OTC on the relevant form as per rules for the enlistment of product along with all the annexures as per the checklist posted on the DRAP official website "www.dra.gov.pk" under the Division of Health & OTC and the fee.

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CHAPTER 2

MANUFACTURE OF ALTERNATIVE MEDICINES USING CRUDE HERBS

4. Application of Building Layout Plan:

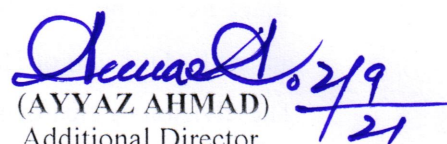
The applicant will apply to the Division of Health & OTC, DRAP for the approval of building lay out. Triplicate copies duly marked sections along with the HVAC drawings (if required), personnel and material flow. The building layout plan will be approved by the said Division as per its SOPs for the approval of building layouts.

5. Application for the grant of enlistment as manufacturer:

The applicant will apply to the Division of Health & OTC on Form-1 along all the annexures as per the checklist posted on the DRAP official website "www.dra.gov.pk" under the Division of Health & OTC including the approved building layout and the fee. The Division of Health & OTC will proceed the application as per the approved SOPs for the grant of enlistment as manufacturer (Form-6).

6. Application for the grant of Product enlistment:

The Form-6 holder will apply to the Division of Health & OTC on the relevant form as per rules for the enlistment of product along with all the annexures as per the checklist posted on the DRAP official website "www.dra.gov.pk" under the Division of Health & OTC and the required fee. The Division of Health & OTC will proceed the application as per the approved SOPs for the grant of enlistment of product.


(AYYAZ AHMAD)

Additional Director,
Division of Health & OTC Products
Drug Regulatory Authority of Pakistan