

No.F.15-1/2022-PEC
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulation & Coordination

“SAY NO TO CORRUPTION”

Subject: - Submission of replies of deferred applications of Form-5 and Form-5A of Human Drugs

I am directed to refer to the subject captioned above. Registration Board in its 339th meeting held on 6-8 August, 2024 deliberated that the deadline for submission of Form-5 and Form-5A of Human Drugs was 07th March 2019. Thereafter, Form-5F (CTD) was implemented. Registration Board observed that firms are submitting replies of applications of Form-5 and Form-5A of Human Drugs deferred in various Registration Board meetings after lapse of long time which is creating hurdle in reducing the pendency of current registration applications. The Board deliberated the matter in detail and decided that replies of applications of Form-5 and Form-5A of Human Drugs deferred in various Registration Board meetings shall be submitted in R&I section of DRAP till 31st December 2024. Replies of such applications submitted after said date shall not be entertained and all such applications shall be considered as disposed off and the applicant firm may submit fresh application on Form-5F which will be considered on its turn in queue of Form 5F.

2. Accordingly, above decision of the Registration Board is hereby circulated for information and compliance by all relevant stake holders /applicants.

(ASIF JALIL)
Deputy Director (PE&R) /
Incharge PEC

Distribution:

- i. Chairman, Pakistan Pharmaceutical Manufacturer's Association, Islamabad.
- ii. Executive Director, Pharma Bureau, Karachi.
- iii. Executive Director, Pakistan Chemist & Druggist Association, Karachi.

Through E-Office:

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- ii. Director (MIS), DRAP for uploading on DRAP's website.
- iii. Director QA< for forwarding to Additional Director / Officer In-charge DRAP Karachi, Lahore, Islamabad, Peshawar, Quetta for circulation to pharmaceutical units located in their respective area of jurisdiction.


Deputy Director (PE&R) /
Incharge PEC