



No. 320-DRB/2022(PE&R)  
Government of Pakistan  
Ministry of National Health Services, Regulations and Coordination  
(Drug Regulatory Authority of Pakistan)  
TF Complex Sector G-9/4

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"SAY NO TO CORRUPTION"

Islamabad, 17<sup>th</sup> October, 2022

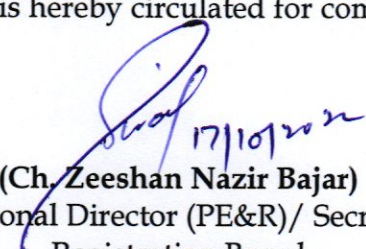
**NOTIFICATION**

Subject: - **Applications submitted on Form 5 / 5-D requiring submission of stability data.**

I am directed to refer to the subject captioned above. Registration Board in its 320<sup>th</sup> meeting held on 29<sup>th</sup> - 31<sup>st</sup> August, 2022 observed that various applications were received on Form 5 / 5-D, which requires submission of stability study data for further processing. The list of such applications is available on official website of DRAP at <https://www.dra.gov.pk/e-services/applications-for-pharmaceutical-drugs/>. Keeping in view the pendency, the Board decided as under:


*"The firms shall initiate the product development and stability studies of submitted applications and intimate to Pharmaceutical Evaluation Cell (PEC) regarding procurement of raw material, initiation of product development and initiation of stability studies, by 31<sup>st</sup> December 2022. For all those applications for which Pharmaceutical Evaluation Cell will not receive any intimation regarding initiation of product development and stability studies, will be placed before the Board for decision."*

2. Accordingly, above decision of Registration Board is hereby circulated for compliance of all relevant stakeholders.

  
(Ch. Zeeshan Nazir Bajar)  
Additional Director (PE&R)/ Secretary,  
Registration Board

**Distribution:**

- i. Director (PE&R)/Chairman, Registration Board.
- ii. Director (MIS), DRAP with request to upload said letter on DRAP's website.
- iii. Additional Director / Officer In-charge DRAP Karachi, Lahore, Islamabad, Peshawar, Quetta for circulation to pharmaceutical units located in their respective area of jurisdiction
- iv. The Executive Director, Pharma Bureau, Karachi.
- v. The Chairman, Pakistan Pharmaceutical Manufacturer's Association, Islamabad.
- vi. The Executive Director, PCDA, Karachi.

  
Additional Director (PE&R)/  
Secretary, Registration Board