



No.F.3-8/2017-RRR (M-272)
Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations & Coordination

"SAY NO TO CORRUPTION"

Islamabad, the 12th October, 2017.

CIRCULAR

Subject: **SUBMISSION OF RENEWAL APPLICATION WITH RESPECT TO POST REGISTRATION VARIATION**

I am directed to refer to the subject captioned above. Registration Board in its 272nd meeting held on 27-28th July, 2017 deliberated on the matter regarding submission of renewal of application towards post-registration variation and decided as follows:

- *No post registration variation shall be considered towards renewal of registered product w.e.f 01st January, 2018.*
- *From 01-01-2018, for all post-registration variation approvals, Registration section of PE&R Division shall mention that "This approval is post registration variation and will not be considered towards renewal of registration".*
- *The approvals of post-registration variation granted previously, although bearing the statement mentioned above, shall be considered towards renewal of respective registered product."*

(Mrs. Tehreem Sara)
Deputy Director (RRR)
For Secretary, Registration Board

Distribution: -

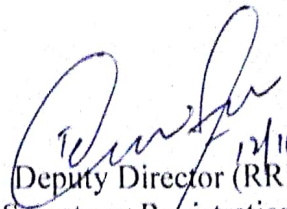
- Chairman, PPMA, Islamabad.
- Executive Director, Pharma Bureau, Karachi.
- Executive Director, PCDA, Karachi.

Copy for further necessary action to: -

- Director, Biological Drugs Division.
- Director (MIS), with the request to upload the same on DRAP's website.
- Additional Director (E&M), DRAP, Islamabad/Lahore/Karachi/Quetta/Peshawar with the request to circulate to all manufacturers/importers in the area of their jurisdiction
- Deputy Director (Reg-I, Reg-II, Reg-III, Reg-IV, Reg-V)

Copy for information to: -

- PS to CEO, DRAP.
- PA to Director (PER)/Chairman, Registration Board.
- Secretary Registration Board.


12/11/2017
Deputy Director (RRR)
For Secretary, Registration Board