Post registration variation Process for biologicals:

Process Description:

Name of Process	Post registration variation Process for registered biologicals.
Name of Business process	Application for post registration variation
Related Laws. Rules and regulations	• Drug Regulatory Authority of Pakistan Act, 2012. • Drugs Act, 1976 • The Drugs (Labeling & Packing) Rules, 1986 • The Drugs (Licensing, Registering & Advertising) Rules, 1976. • The Drugs (Specification) Rules, 1978.
Input & Criteria to enter/begin the business process	• A valid Drug Manufacturing License (Form 2) • For Finished product Import; A valid Drug Sale License and Sole Agency Agreement • A valid Certificate of Registration
Activities and associated documentary requirements	Initiation of post registration variation of biological (drug) product: 1. Applicant shall submit application for any post registration variation with requisite documents and fee. 2. DRAP receives, scrutinizes and evaluate the applications and requisite documents as per SOP approved by Registration Board on FIFO basis. 3. If the application is in-complete, DRAP informs the applicant with observation note. One reminder is issued in case applicant fails to reply in stipulated time period. 4. After rectification of shortcomings by applicant, Biological Evaluation & Registration Division DRAP prepares summary. a. For Chairman Registration Board for functions / variations for which Chairman Registration Board is authorized. b. For functions / variations not falling in above category, cases are presented before Registration Board. 5. Chairman RB / Registration Board takes final decision. 6. BE&R Division issues approval letters for post registration variation to the applicant. 7. In case of rejection of application by RB or its Chairman, applicant has the right to file appeal within 60 days before the Appellate Board.
Output Criteria to exit the business process	• Approval letter for post-registration variation from DRAP office. • Legal Reference: Drug Regulatory Authority of Pakistan Act, 2012, The Drug Licensing, Registering & Advertising) Rules, 1976, The Drugs (Labeling & Packing) Rules, 1986 and The Drugs (Specification) Rules, 1978.
Time required to exit the business	• Minimum: 01 months • Maximum: 03 months

process	
Fee	The updated fee structure of regulatory functions can be accessed on https://www.dra.gov.pk/publications/regulatory-fees/.