

APPLICATION PROCESS AND REQUIREMENTS FOR POST-APPROVAL CHANGES OF PHARMACEUTICAL PRODUCTS

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I. BACKGROUND/RATIONALE

Prior to the full adoption and implementation of the Association of Southeast Asian Nations (ASEAN) Common Technical Dossier (ACTD) and Common Technical Requirements (ACTR), Marketing Authorization Holders (MAHs) referred to the provisions of PSD Memo 02-05, “Updated Checklist of Requirements for Request of Amendment and Revalidation”, FDA Circular No. 2011-002, “Application for Revisions/Updates in the Package Insert, Patient Leaflet Information, Prescribing Information, Core Data Sheet, and Basic Succinct Statement”, and other national regulations to support post-approval changes to their registered products. However, the said regulations proved to be insufficient to cover many other possible post-approval change scenarios. Therefore, a more comprehensive guideline is needed to address in detail the requirements and applications process for post-approval changes.

The ASEAN Variation Guideline (AVG) for Pharmaceutical Products was established (a) to take into account technical and scientific progress of pharmaceutical products after they have been approved for marketing by the Drug Regulatory Authority (DRA) and (b) to support any post-approval changes that may be required to enable the pharmaceutical products to be manufactured. The AVG is intended to provide supportive information on the requirements for submission of variation application to implement a change to a pharmaceutical product. Although the AVG is a comprehensive guideline, some post-approval changes not covered here are subject to country-specific requirements.

In line with the provisions of Administrative Order No. 2013-021, “Adoption of the Association of Southeast Asian Nations (ASEAN) Common Technical Dossier (ACTD) and Common Technical Requirements (ACTR) for the Registration of Pharmaceutical Products for Human Use”, the Food and Drug Administration hereby promulgates the revised application process and requirements for instituting Post-Approval Changes (PACs) to registered pharmaceutical products, which shall cover both the AVG and country-specific requirements.

II. OBJECTIVES

The objectives of this Circular are:

- 1) To promulgate the revised requirements in instituting post-approval changes to registered pharmaceutical products, incorporating the AVG and countryspecific requirements; and
- 2) To provide the application process for instituting post-approval changes.

III. SCOPE

This Circular shall apply to all manufacturers, traders and distributors (e.g. exporters, importers and wholesalers) of pharmaceutical products covered by ACTD/ACTR. In the absence of a more specific regulation, the provisions of this Circular also serve as the requirements for manufacturers, traders and distributors of single and multi-component vitamin and mineral products, vaccines and biologics, traditional medicines, over-the-counter preparations, household remedies, medical gases, and veterinary products.

IV. IMPLEMENTING DETAILS

A. Eligibility

Any MAH of a pharmaceutical product may apply for PAC, provided:

- The MAH has a valid License to Operate (LTD); and
- The pharmaceutical product is covered by a valid Certificate of Product Registration (CPR); provided further, that if the CPR has already expired, the pharmaceutical product is applied for regular renewal registration.

B. Classification

Post-approval changes may be classified according to reference:

(a) ASEAN Variation Guideline

- Major Variation (MaV)
- Minor Variation (MiV)
- Prior Approval (MiV-PA)
- Notification (MiV-N)

(b) Country-Specific Requirements

- MaV
 - Additional route of administration
 - Change of manufacturing site (same subsidiary) of the drug product
- MiV-PA
 - Change of capsule color
 - Change of brand name
 - Change of MAH
 - Reclassification (ex. Over-the-counter [OTC] to Prescription, OTC to household remedy [HR])
- Such other PACs not covered by AVG

C. Application Process

An application for PAC may be submitted any time during the validity of the CPR; provided, that if such application is submitted at the end of the CPR validity, it shall be incorporated in the application for regular renewal registration.

All applications for PACs shall follow the submission process and requirements as prescribed in the latest issuance of FDA.

D. Requirements

The requirements shall follow the AVG, latest revision, which shall be posted and made available at the FDA website. For changes requiring prior approval (i.e., AVG/Country-Specific Requirements MaV and MiV-PA), a Letter of Request for Post-Approval Change shall be included in the application, indicating the specific type of PAC and all affected products. A template Letter of Request is attached as Annex A*.

For changes classified under minor variation-notification, application is on a per product submission. A notification form shall be included in the application, in addition to the requirements of AVG. A template Notification is attached as Annex B*.

For PACs following Country-Specific Requirements, the requirements are attached as Annex C*. For other PACs that may arise and are not covered by this Circular, the requirements shall be determined by FDA as deemed appropriate/applicable.

All PACs to a specific product may be submitted under a single application. In case of recurring documentary requirements, a single copy may be submitted.

For verification purposes, FDA may require additional information, as deemed necessary, to ensure that the product maintain its safety, efficacy, and quality.

E. Approval

A Certificate/Clearance shall be issued by FDA indicating each PAC approved.

F. Fees

The appropriate fees as prescribed under existing regulations shall apply, including the Legal Research Fund (LRF). The payment shall be on a per product, per change basis. A matrix of fees is attached as Annex D.

The fees for the following PACs shall be equivalent to initial registration schedule of fees:

- MaV-I: Change and/or additional indication/dosing regimen/patient population/ inclusion of clinical information extending the usage of the product
- MaV-4: Addition or replacement of the manufacturing site of the drug product
- MaV-10: Qualitative or quantitative change of excipient
 - a) For immediate release oral dosage forms (as per Level 2 and 3, Part III Components and Composition, SUPAC guideline)
 - b) For modified release oral dosage forms
 - c) For other critical dosage forms such as sterile preparations
- MaV-11: Quantitative change in the coating weight of tablets or weight and/or size of capsule shell for modified release oral dosage form
- MaV-12: Change in primary packaging material for sterile product
 - a) Qualitative and quantitative composition and/or
 - b) Type of container and/or
 - c) Inclusion of primary packaging material
- MaV-13: Change or addition of pack size/fill volume and/or change of shape or dimension of container or closure for a sterile solid and liquid drug product (unless the change is dimension, i.e. wide-mouth bottles vs. narrow-mouth bottles)

- MiV-PA15: Qualitative or quantitative change of excipient
 - a) For immediate release oral dosage forms (as per Level 1, Part III Components and Composition, SUPAC guideline)
 - b) For other non-critical dosage forms (e.g. oral liquid, external preparation)
- MiV-PA16: Quantitative change in coating weight of tablets or weight and/or size of capsule shell for immediate release oral dosage form
- MiV-PA17: Change of the colouring/flavouring agent of the product [addition, deletion or replacement of colourant(s)/flavour(s)]
- MiV-PA28: Change in primary packaging material for non-sterile product
 - a) Qualitative and quantitative composition and/or
 - b) Type of container and/or
 - c) Inclusion of primary packaging material
- Change of manufacturing site (same subsidiary) of the drug product

FDA, from time to time, may prescribe changes in fees, which shall be promulgated in an appropriate regulation.

V. TRANSITORY PROVISIONS

The revised requirements and application process for post-approval changes shall only apply to incoming post-approval change applications; all pending applications and their compliances shall not be covered by this Circular.

VI. REPEALING CLAUSE/SEPARABILITY CLAUSE

Provisions in previous circulars and memoranda that are inconsistent with this Circular are hereby withdrawn, repealed, and/or revoked accordingly.

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Circular shall not be affected.

VII. EFFECTIVITY

This Circular shall take effect 01 April 2014

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* Text Available at the Office of the National Administrative Register, U.P. Law Complex, Diliman, Quezon City.

Annex D

Matrix of Fees

Type of PAC

Fee per product per PAC

Regular PACs, including change of capsule color

P500 + LRF

With FDA Clinical Review for revision/update of PI, PIL, Prescribing Information, Core Data Sheet and Basic Succinct statement

P500 + LRF

With FDA Clinical Review for additional indication

With Subsequent Labeling
Amendment (per product/strength)

P2,500 + LRF

P500 + LRF

Change or addition of brand name

P2,500 + LRF + P510 (for each brand name proposed)

Shelf life extension/reduction

P1,000 + LRF

Equivalent to Initial Registration, including Additional Route of Administration

Unbranded

P10,000 + LRF

Branded

P15,000 + LRF

Monitored Release Status

P20,000 + LRF (for three years) + P20,000 + LRF for additional two years as per FDA Circular 2013-004)

Reclassification

P3,000 + LRF

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