FDA CIRCULAR
No. _____

SUBJECT: **Implementation of Abridged and Verification Review Pathways for New Drug, Initial Registration and Post-Approval Changes Applications of Drug Products, including Vaccines and Biologicals**

I. BACKGROUND

As pharmaceutical supply chains become more globalized and complex, regulatory oversight increases as well in complexity, on top of an increasing need for financial and technical resources. It is, therefore, strategic to establish regulatory reliance and cooperation practices among national regulatory authorities, in order to address individual regulatory gaps in a more efficient and effective manner. With the issuance of Administrative Order (AO) No. 2020-0045, entitled, "Establishing Facilitated Registration Pathways for Drug Products, including Vaccines and Biologicals", the Food and Drug Administration (FDA) recognized that instituting good reliance practices would be impactful towards facilitating access to medicines, by producing more efficient regulatory mechanisms.

The World Health Organization defines reliance as "*the act whereby the national regulatory authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others*".

In applying regulatory reliance, the FDA shall be streamlining its regulatory review to accelerate the registration process for medicines, by leveraging against product regulatory assessments made by reference drug regulatory authorities (RDRAs). Simultaneously, strengthened post-marketing surveillance shall ensue; whilst, continuous improvement in building FDA's institutional capacity to effectively oversee innovative and complex medical technologies shall remain in the long term. Thus, pursuant to Republic Act (RA) No. 3720 as amended by RA No. 9711, and in line with the directives for process re-engineering under RA No. 11032, the FDA hereby implements this Circular as a pragmatic approach to institutionalizing regulatory reliance.

II. OBJECTIVE

This Circular aims to provide the implementing guidelines on facilitated registration pathways (FRPs) through abridged review or verification review of drug products, including vaccines and biologicals.

III. SCOPE AND COVERAGE

This Circular shall apply to all local drug manufacturers, traders and distributors intending to place in the local market or apply for variation of drug products with existing valid approval/s from reference regulatory agency/ies. This shall include applications of new drug, initial registration and post approval changes of drug products, including vaccines and biologicals.

This Circular shall not apply to pending registration applications.

IV. IMPLEMENTING DETAILS

A. Reference Drug Regulatory Authorities (RDRAs)

RDRAs refer to national or regional authorities being relied upon by the FDA. The list of RDRAs is provided under Annex A of this Circular, subject to revisions from time to time.

B. Eligibility Criteria

The eligibility criteria provided under AO No. 2020-0045 shall apply for applicants availing of the FRP. The follow points are hereby clarified:

1. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site(s), release and shelf-life specifications, and primary packaging, must be the same as those currently approved by the chosen RDRA at the time of submission. In addition, a report of stability studies conducted under climatic Zone IVB (hot and very humid), with the required minimum time period covered by data at submission, minimum number of batches, and storage conditions for accelerated and long-term conditions shall be provided.
2. The proposed indication(s), dosing regimen(s), patient group(s) and/or direction(s) for use should be same to those approved by the RDRAs.
3. The applicant company may avail of the FRP for product applications within two (2) years from the date of approval of the RDRA.
4. Any product which has been issued with a disapproval, previously withdrawn, suspended, approved via appeal process, or which has pending deferral by any RDRAs due to quality, safety, and/or efficacy reasons shall not be eligible for FRP.

C. Requirements

1. Abridged Review

a. A formal, written request from the applicant/Marketing Authorization Holder (MAH) notifying the FDA of its intent to avail of the FRP, identifying the RDRA(s). For applicant/MAH availing of the abridged review, a primary RDRA must be identified.

b. A declaration letter signed by the Head of Regulatory Office of the product owner/MAH stating full compliance with the eligibility requirements provided under AO No. 2020-0045.

c. Proof of approval from at least one (1) RDRA, which may either be:

For New Drug or Initial Registration:

i. A valid Certificate of Pharmaceutical Product (CPP), indicating the registration status of the product; and
ii. A valid Good Manufacturing Practice (GMP) Certificate together with Certificate of Free Sale (CFS).

For Post-Approval Changes:

iii. A Letter of Approval or Notification.

d. Complete International Council for Harmonisation of Technical Requirements for Pharmaceutical for Human Use (ICH) Common Technical Document (CTD) or ASEAN Common Technical Dossier (ACTD) data requirements following existing guidelines shall be submitted to FDA.

e. Assessment Report from the identified RDRA:

i. A complete, unredacted or unedited copy of the assessment report including the assessment on the quality, nonclinical, and clinical reviews, product approval conditions, and the final and approved product labeling shall be provided.
ii. For products with post-approval variation/s, all assessment reports and/or documents concerning the post-approval variations, including a tabulated summary of variation approvals from the RDRA, shall also be provided.
iii. All annexes of the assessment report shall be submitted.
iv. All submitted documents shall be written/translated in English.
v. Question and answer (Q&A) documents

2. Verification Review

a. A formal, written request from the applicant/MAH notifying the FDA of its intent to avail of the FRP, identifying the RDRA(s). In addition, the primary RDRA must be identified for verification review.

b. A declaration letter signed by the Head of Regulatory Office of the product owner/MAH stating full compliance with the eligibility requirements provided under AO No. 2020-0045.

c. Proof of approval from at least two (2) RDRAs, which may either be:

For New Drug or Initial Registration:

i. A valid Certificate of Pharmaceutical Product (CPP), indicating the registration status of the product; and
ii. A valid Good Manufacturing Practice (GMP) Certificate together with Certificate of Free Sale (CFS).

For Post-Approval Changes:

i. A Letter of Approval or Notification

d. Complete ICH CTD or ACTD data requirements following existing guidelines shall be submitted to FDA.

e. Assessment Report from the identified RDRA:

i. A complete, unredacted or unedited copy of the assessment report from the primary RDRA, including the assessment on the quality, nonclinical, and clinical reviews, product approval conditions, and the final and approved product labeling shall be provided.
ii. For verification review, the Question & Answer (Q&A) documents between the MAH and the RDRA shall be included.
iii. For products with post-approval variation/s, all assessment reports and/or documents concerning the post-approval variations, including a tabulated summary of variation approvals from the RDRA shall also be provided.
iv. All annexes of the assessment report shall be submitted.
v. All submitted documents shall be written/translated in English.
vi. The submission of a public assessment report is deemed unacceptable.

D. Review and Evaluation

1. Approval by the RDRAs does not oblige the FDA to approve the application. The FDA retains its prerogative to assess applications and apply judgements that consider benefits and risks as it applies to the Philippine context.

2. The FDA may request additional supporting documents, as deemed necessary, to ensure the safety, efficacy, and quality of the product intended for registration.

E. Timelines

Type of Facilitated Review	Timeline (Working Days)
Abridged Review	90
Verification Review	45

F. Fees

The appropriate fees as prescribed under existing regulations shall apply, including a Legal Research Fee (LRF), following AO No. 50 s. 2001 or any amendment or latest issuance thereafter.

V. PENALTY CLAUSE

The applicable penalties under Republic Act No. 9711 and its Implementing Rules and Regulations and other laws shall apply.

VI. SEPARABILITY CLAUSE

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

VII. EFFECTIVITY

This Circular shall take effect fifteen (15) days following its publication in a newspaper of general circulation and upon filing to the University of the Philippines Law Center – Office of the National Administrative Register.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

ANNEX A

List of Recognized RDRAs

1. Australia – Therapeutic Goods Administration (TGA)
2. Canada – Health Canada (HC)
3. European Union (EU) – European Medicines Agency (EMA)
4. Japan – Pharmaceuticals and Medical Devices Agency (PMDA)
5. Switzerland – Swissmedic
6. United Kingdom – Medicines and Healthcare Products Regulatory Agency (MHRA)
7. United States of America (USA) – US Food and Drug Administration (FDA)