

## ANNEX B

### Sworn Assurance

I, (name of Head of Regulatory Office), (legal age), (citizenship), resident of (address), after being sworn according to law, hereby depose and state:

1. I am the Head of the Regulatory Office of (Name of Applicant Company) with business address at (address).
2. I am applying for the issuance of a (Certificate of Product Registration or Variation) of the (name of product) under a Facilitated Pathway Review under AO No. 2020-0045.
3. That the product being applied, including but not limited to the composition/ formulation, strength, manufacturing of finished product and active pharmaceutical ingredients, specifications, product information, and others, at the time of the submission, is the same in all respects as the product approved by the following RDRA/s:

RDRA	Date of RDRA approval
1.	1.
2.	2.
.	.
.	.
.	.

4. The documents submitted to the RDRA are in accordance with the requirements of ICH/ACTD, and if not, I hereby submit the necessary technical documents to comply with the dossier requirements and format following existing guidelines.
5. The product and its intended use has not been rejected, withdrawn, suspended, revoked, or has pending deferral by any RDRA due to quality, safety, or efficacy reasons.
6. That there is full compliance with the eligibility requirements provided under AO No. 2020-0045, and all data and information submitted in connection with this application as well as other submissions in the future are true and correct and reflect the total information available.
7. I understand that the Philippine Food and Drug Administration (FDA) may verify through both government and private entities the authenticity of all the information and documents submitted. I fully consent and authorize the Philippine FDA to conduct such verification for purposes of evaluation of my application.

IN WITNESS WHEREOF, I have hereunto set my hand this (date) in (city).

(Name of Head of Regulatory Office)  
Affiant

SUBSCRIBED AND SWORN to before me this \_\_\_\_\_ at \_\_\_\_\_,  
Philippines.

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