FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Philippines	**Agency Name:** Food and Drug Administration (FDA)	
Name of FRP: Facilitated Registration of Applications		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: Click here to enter a date.		
1. Facilitates activities during development	**2. Accelerates the regulatory review process**	**3. Relies on or recognizes a prior regulatory decision**
☐	☒	☒
Is a Guidance or SOP describing how to apply this FRP publicly available?	Yes- see reference below	
When should the FRP be requested?	At the time of the submission	
Does the agency provide assistance/advice to the sponsor?	Yes- For any product type	
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	1. Products to be manufactured exclusively for export 2. New drug products considered to be a major therapeutic advance 3. The first 5 products of newly licensed establishments without any registered drug product yet to its name 4. Products for government programs and projects 5. Imported prequalified vaccines **In the Philippines, drug products are classified into the following: 1) New Drugs or New Chemical Entities 2) Biological Products 3) Generic Drugs 4) Traditionally-Used Herbal Products 5) Herbal Medicines 6) Household Remedies 7) Over-the-Counter Preparations 8) Veterinary Drugs 9) Medical Gases 10) Stem Cell Products	
Must the product address an unmet medical need or serious condition?	Negotiable	
If a fee is required, what is the amount (in US$ equivalent)	Click here to enter text.	
Total target (agency) time for assessment (calendar days)	A maximum of 90 calendar days is given by the FDA for facilitated applications, excluding stop-clocks due to noted deficiencies.	
Total target (company) time for responses to agency questions (If stated)	Click here to enter text.	
Select one of the following (* see definitions at end of document)		
Is this a verification review (a recognition pathway)?*	**Is this an abridged* review (selected dossier portions)? (a reliance pathway)?***	**Is this a full* review of all parts of the dossier?**

FRPath.org Country and FRP Information Input Form		
☐	☐	☒
If this is a reliance or recognition pathway, what are the accepted reference agencies?	Click here to enter text.	
How many reference agency decisions are required?	Click here to enter text.	
Does this FRP require submission of Assessment Reports from prior decisions?	Unredacted	
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Yes at time of submission	
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Click here to enter text.	
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, this process is not through a Regional Regulatory Initiative.	
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Click here to enter text.	
How are queries to the companies sent?	Choose an item.	
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.	
Post-authorization study commitments	Always required	
For how long is the initial approval or designation valid?	4-5 years	
Any other details you wish to provide?	- For a company to be able to market a drug product in the Philippines, securing a marketing authorization in the form of a Certificate of Product Registration (CPR) is necessary. A CPR covering a particular drug product shall be a prima facie evidence of the registrant's marketing authority for the said drug product in connection with the activities permitted pursuant to the issuance of a LTO. - Orphan drugs are registered following a facilitated registration process and may fall either through the abovementioned categories (or as biological preparations), or may be accessed by patients using a Compassionate Special Permit (CSP). A CSP is a special permit signed by the	

	FDA Director granting a Specialized Institution (SI) and Specialty Society (SS) the privilege to avail of an unregistered drug and device product through a certain licensed establishment for certain kind/type of patients, specific volume and period. Patients having the following conditions are allowed to use CSP: 1) Acquired Immune Deficiency Syndrome (AIDS) 2) Cancer 3) Life-threatening conditions. A maximum of 15 calendar days is given by the FDA in the processing of CSP. - CPRs issued by the FDA are given 5 year validity. For continuous marketing authorization after the validity, the MAH shall apply for renewal of registration. Submission of the application for renewal shall be on or 120 days before the expiration date of the CPR. Renewal shall be accepted unless the prescribed renewal fee is paid. There shall be automatic renewal of the CPR when the following conditions are satisfied: (i)The application is filed before the expiration date of the registration; (ii)The prescribed renewal fee is paid upon filing of the application; and (iii)A sworn statement indicating no change or variation whatsoever in the product is attached to the application.
Date of this update	5 February 2020.
References	1. Drug Approval System of the Philippines. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=12&cad=rja&uact=8&ved=2ahUKEwifrsrar7rnAhUMLVAKHaZhAyAQFjALegQIBRAB&url=http%3A%2F%2Fwww.nifds.go.kr%2Fbrd%2Fm_95%2Fdown.do%3Fbrd_id%3Dboard_mfds_411%26seq%3D22991%26data_tp%3DA%26file_seq%3D2&usg=AOvVaw1abhBqh1Y-elVCEYejfbIE Accessed on 5 February 2020.

*Definitions:

Verification review: A checklist review based on recognition of a prior regulatory decision. Recognition is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of economy A is sufficient to meet the regulatory requirements of economy B.

Abridged review: An abbreviated review of selected portions of the dossier and the reliance on prior assessment decisions. Reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Full review: A comprehensive review of all components of the dossier. This may or may not be CPP-dependent. This may form part of a reliance or recognition pathway.