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Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: Ghana	**Agency Name:** Food and Drugs Authority Ghana (FDA Ghana)	
Name of FRP: Alternative/non routine authorization application pathways – RELIANCE ROUTE		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 1/2/2019		
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?	The FDA shall activate the reliance pathway to facilitate regulatory decisions either on a case by case basis or at the explicit request of the applicant.	
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	Allopathic drugs for human use, biological products and medical devices.	
Must the product address an unmet medical need or serious condition?	Negotiable	
If a fee is required, what is the amount (in US$ equivalent)	- Registration of imported allopathic products – 3 years = USD3600 - Registration of imported New Chemical Entities/New Drugs = USD5400 - Registration of local allopathic products – 5 years = GHC2000 [USD363]	
Total target (agency) time for assessment (calendar days)	Applications under this category shall be processed within **3 months**.	
Total target (company) time for responses to agency questions (If stated)	Responses to query submitted to the FDA by applicant not later than 12 months from date of first deferral, 6 months on second deferral and 3 months on third deferral. If product registration committee rejects the application, you may appeal decision within 60 days.	
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?**
☐	☒	☐
If this is a reliance or	ICH founding regulatory member state or region (such as EC (EMA),	

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recognition pathway, what are the accepted reference agencies?	United States (United States Food and Drugs Administration), Japan (MHLW/PMDA)) or an ICH standing regulatory member state or region (such as Canada (Health Canada), Switzerland (Swissmedic). Products registered by TGA of Australia, Iceland, Liechtenstein and Norway may be considered through the reliance route on a case by case basis. Product should have been evaluated and listed as an output of the West African Medicines Harmonization initiative of the Economic Community of West African States (ECOWAS).
How many reference agency decisions are required?	Not stated
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?	Analytical reports from laboratories which are WHO Prequalified or ISO/IEC 17025:2017 accredited and awarded by an ILAC member. Latest, valid European Certificate of Suitability (CEP) (including any annexes) should be provided where applicable.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No; it is not through an RRI.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Yes; list countries in which the product has been registered (Attach Certificate(s) of registration. Alternatively, the product must have been registered and/or granted Marketing Authorization (MA) for more than 6 months in either an ICH founding regulatory member state or region (such as EC (EMA), United States (United States Food and Drugs Administration), Japan (MHLW/PMDA)) or an ICH standing regulatory member state or region (such as Canada (Health Canada), Switzerland (Swissmedic). Products registered by TGA of Australia, Iceland, Liechtenstein and Norway may be considered through the reliance route on a case by case basis. Product should have been evaluated and listed as an output of the West African Medicines Harmonization initiative of the Economic Community of West African States (ECOWAS).
How are queries to the companies sent?	At specified times during the assessment
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
Post-authorization study	Always required

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commitments	
For how long is the initial approval or designation valid?	2-3 years
Any other details you wish to provide?	- Alternative/non routine authorization application pathways = Reliance Pathway & Verification Pathway. - FDA reserves the right to subject all submissions for approval to an 'abridged' evaluation of a certain part of the application (e.g. relevant to use under local condition) such as product quality data in relation to climatic conditions & distribution infrastructure and a benefit-risk assessment in relation to use in the local ethnic population, medical practice/culture and patterns of disease and nutrition. - Full product development dossier is required. - The application shall be identical to that submitted, evaluated and approved by the well-resourced NRA or reference NRA.
Date of this update	13 November 2019
References	1. Approved Fees Schedule https://fdaghana.gov.gh/images/stories/pdfs/Quick%20links/FDA%20FEES%20SCHEDULE.pdf Accessed on 10 November 2019 2. Timelines for medical products registration https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/DER/2019/Timelines%20for%20Medicinal%20Product%20Registration.pdf Accessed on 10 November 2019 3. FDA Reliance Policy https://fdaghana.gov.gh/images/stories/pdfs/Quick%20links/Policy/FDA%20RELIANCE%20POLICY.pdf Accessed on 10 November 2019

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.

By submitting this form, I agree that the information is true to the best of my knowledge and I consent that it can be used without restriction by FRPath.