FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: United States of America	**Agency Name:** United States Food and Drug Administration	
Name of FRP: FDA Priority Review		
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	An application for a drug will receive priority review designation if it is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. In addition, specific statutory provisions provide for priority review for various types of applications. A priority designation is intended to direct overall attention and resources to the evaluation of such applications. Designation of a drug as "Priority" does not alter the scientific/medical standard for approval or the quality of evidence necessary.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	FDA User Fee Programs
Total target (agency) time for assessment (calendar days)	A Priority Review designation means FDA's goal is to take action on an application **within 6 months** (compared to 10 months under standard review). FDA informs the applicant of a Priority Review designation within 60 days of the receipt of the original BLA, NDA, or efficacy supplement.
Total target (company) time for responses to agency questions (If stated)	Communication with the Agency is a critical aspect of expedited programs. FDA will strive to provide a timely response to a sponsor's inquiry regarding an expedited development program. It is equally critical that a sponsor respond promptly to FDA's inquiries. This applies to formal meetings and related inquiries, written correspondence, and other interactions. In addition to the many types of formal meetings and correspondence the Agency offers to sponsors, additional considerations for sponsors of

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	expedited programs are highlighted in this section.

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 recognition pathway, what are the accepted reference agencies?	No, this is not a reliance or recognition pathway.
How many reference agency decisions are required?	Not applicable.
Does this FRP require submission of Assessment Reports from prior decisions?	Not applicable
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Not applicable
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Not applicable.
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?	Not applicable.
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?	Choose an item.
Any other details you wish to provide?	- Prior to approval, each drug marketed in the United States must go through a detailed FDA review process. In 1992, under the Prescription Drug User Act (PDUFA), FDA agreed to specific goals for improving the drug review time and created a two-tiered system of review times – Standard Review and Priority Review. - A *Priority Review* designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or

	effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. - Sponsors may request priority review designation when they submit an original BLA, NDA, or efficacy supplement. The Agency does not anticipate that priority review designation requests will be made after the filing of a BLA, NDA, or efficacy supplement. - Significant improvement may be demonstrated by the following examples: 1. evidence of increased effectiveness in treatment, prevention, or diagnosis of condition; 2. elimination or substantial reduction of a treatment-limiting drug reaction; 3. documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes; or 4. evidence of safety and effectiveness in a new subpopulation. - FDA decides on the review designation for every application. However, an applicant may expressly request priority review as described in the Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. It does not affect the length of the clinical trial period. - After priority review designation is assigned, the timeline will not change during the first review cycle, even if a redetermination of review status is made because of approval of other drugs, availability of new data, or submission of a request for formal dispute resolution by the applicant. In addition, applications filed over protest are assigned a standard review. If the application is resubmitted after FDA's refuse-to-file decision or if the application is withdrawn before FDA's action and resubmitted, FDA will make its determination of review designation based on the resubmitted application.
Date of this update	11 APRIL 2020
References	1. Priority Review. https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review Accessed on 11 April 2020. 2. Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics. https://www.fda.gov/media/86377/download

*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.