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 (USFDA)	
Name of FRP: FDA Fast Track		
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?	Before the marketing authorisation 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	The Fast Track program facilitates the expedited development and review of **new drugs or biologics** that are intended to: 1. treat serious or life-threatening conditions and 2. demonstrate the potential to address unmet medical needs. Sponsors typically request Fast Track Designation during the IND phase of drug development. *A drug that receives Fast Track designation is eligible for some or all of the following: 1. More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval 2. More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers 3. Eligibility for *Accelerated Approval* and *Priority Review*, if relevant criteria are met 4. Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA.
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount	FDA User Fee Programs

FRPath.org Country and FRP Information Input Form	
(in US$ equivalent)	
Total target (agency) time for assessment (calendar days)	FDA will review the fast track designation request and make a decision **within sixty days** based on whether the drug fills an unmet medical need in a serious condition. Once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.
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?**
☐	☐	☒

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

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For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions. - Determining whether a condition is serious is a matter of judgment, but generally is based on whether the drug will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the condition, if left untreated, will progress from a less severe condition to a more serious one. AIDS, Alzheimer's, heart failure and cancer are obvious examples of serious conditions. However, diseases such as epilepsy, depression and diabetes are also considered to be serious conditions. - Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. - Fast Track designation must be requested by the drug company. The request can be initiated at any time during the drug development process. - Title VIII of FDASIA (implemented July 9, 2012), Generating Antibiotic Incentives Now (GAIN), provides incentives for the development of antibacterial and antifungal drugs for human use intended to treat serious and life-threatening infections. Under GAIN, a drug may be designated as a qualified infectious disease product (QIDP) if it meets the criteria outlined in the statute. A drug that receives QIDP designation is eligible under the statute for fast track designation (upon request) and priority review.
Date of this update	11 APRIL 2020
References	1. Fast Track. https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track Accessed on 11 April 2020. 2. Fast Track Designation Requests. https://www.fda.gov/drugs/ind-activity/fast-track-designation-requests Accessed on 11 April 2020. 3. Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics.

*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.

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.