A User Guide To FDA's
Expedited Programs For Serious Conditions

Below are key elements of FDA's four expedited drug development and review programs, including qualifying criteria, features and benefits, timelines and other considerations for sponsors. The chart was adapted by "The Pink Sheet" from FDA's May 2014 final guidance, "Expedited Programs for Serious Conditions – Drugs and Biologics."

Key Elements	Fast Track	Breakthrough Therapy	Accelerated Approval	Priority Review
1 Qualifying Criteria	• A drug that is intended to treat a serious condition *AND* nonclinical or clinical data demonstrate the potential to address unmet medical need *OR* • A drug that has been designated as a qualified infectious disease product (QIDP)[1]	• A drug that is intended to treat a serious condition *AND* preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies	• A drug that treats a serious condition *AND* generally provides meaningful advantage over available therapies *AND* demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit (i.e., an intermediate clinical endpoint)	• An application (original or efficacy supplement) for a drug that treats a serious condition *AND* if approved, would provide a significant improvement in safety or effectiveness *OR* • Any supplement that proposes a labeling change pursuant to a report on a pediatric study *OR* • An application for a drug that has QIDP designation[1] *OR* • Any application or supplement for a drug submitted with a priority review voucher[2]
2 Features & Benefits	• Actions to expedite development and review • Rolling review	• Intensive guidance on efficient drug development • Organizational commitment • Rolling review • Other actions to expedite review	• Approval based on an effect on a surrogate or intermediate clinical endpoint that is reasonably likely to predict a drug's clinical benefit	• Shorter clock for review of marketing application (6 months compared to the 10-month standard review)[3]
3 When To Submit Request For Designation/ Pathway	• With IND or after • Ideally, no later than the pre-BLA or pre-NDA meeting	• With IND or after • Ideally, no later than the end-of-Phase II meeting	• The sponsor should ordinarily discuss the possibility of accelerated approval with the review division during development, supporting, for example, the use of the planned endpoint as a basis for approval and discussing the confirmatory trials, which should usually be already under way at the time of approval	• With original BLA, NDA or efficacy supplement
4 FDA Response Timelines	• Within 60 calendar days of receipt of request	• Within 60 calendar days of receipt of request	• Not specified	• Within 60 calendar days of receipt of original BLA, NDA or efficacy supplement
5 Additional Considerations	• Designation may be rescinded if product no longer meets fast-track qualifying criteria[4]	• Designation may be rescinded if product no longer meets breakthrough therapy qualifying criteria[4]	• Promotional materials submitted for pre-approval review • Confirmatory trials to verify and describe the anticipated effect on IMM or other clinical benefit • Subject to expedited withdrawal	• Designation will be assigned at the time of original BLA, NDA or efficacy supplement filing

[1] The FDA Safety and Innovation Act's Generating Antibiotic Incentives Now provisions outline criteria for obtaining designation as a qualified infectious disease product, and these QIDPs are eligible for fast-track designation and priority review.

[2] Vouchers will be granted to companies submitting applications for drugs for the treatment or prevention of certain tropical diseases and for treatment of rare pediatric diseases; if those drugs are approved, the voucher can be submitted along with another drug application to obtain priority review for that product.

[3] As part of its commitments in PDUFA V, FDA established a review model, the Program. It applies to all new molecular entity NDAs and original BLAs received from Oct. 1, 2012, through Sept. 30, 2017. For such applications, the PDUFA review clock now begins after a 60-calendar-day review period that starts on the date FDA received the original submission.

[4] A sponsor also may withdraw fast-track or breakthrough designation if it is no longer supported by emerging data or the drug development program is no longer being pursued.