
Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

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Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics

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Guidance for Industry¹

Expedited Programs for Serious Conditions – Drugs and Biologics

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I. INTRODUCTION

The following four FDA programs are intended to facilitate and expedite development and review of new drugs² to address unmet medical need in the treatment of a serious or life-threatening³ condition: fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation (see [section IV](#) for an overview of the programs). The purpose of this guidance for industry is to provide a single resource for information on FDA's policies and procedures for these four programs as well as threshold criteria generally applicable to concluding that a drug is a candidate for these expedited development and review programs.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The programs described in this guidance are intended to help ensure that therapies for serious conditions are approved and available to patients as soon as it can be concluded that the therapies' benefits justify their risks. The Agency first formally articulated its thinking on expediting the availability of promising new therapies in regulations codified at part 312, subpart E (21 CFR part 312).⁴ The subpart E regulations are intended to speed the availability of new therapies to patients with serious conditions, especially when there are no satisfactory alternative therapies, while preserving appropriate standards for safety and effectiveness. The regulations

¹ This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

² For the purposes of this guidance, all references to *drugs* or *drug products* include both human drugs and biological drug products regulated by CDER and CBER unless otherwise specified.

³ 1. Whether a Condition Is Serious explains that all references to serious conditions include life-threatening conditions.

⁴ Food and Drug Administration, Interim Rule, Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Procedures for Drugs Intended to Treat Life-Threatening and Severely Debilitating Illnesses (53 FR 41516, October 21, 1988).

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