Exclusivity and Generic Drugs: What Does It Mean?

Initial Exclusivities for New Drugs

Exclusivity is a period of time when a brand-name drug is protected from generic drug competition. There are different exclusivities for different situations. Exclusivity is designed to promote a balance between new drug innovation and generic drug competition.

5 years — New Chemical Entity (NCE) Exclusivity

In most cases, a brand-name drug with a new active moiety has a **five-year** exclusivity.

7 years — Orphan Drug Exclusivity (ODE)

A new brand-name drug for a disease or condition that affects fewer than 200,000 people in the United States (or that affects more people but for which the drug company still has no hope of covering the development costs) has a **seven-year** exclusivity.

3 years — New Clinical Investigation Exclusivity

A brand-name drug with an active ingredient that has been approved before may be awarded a **three-year** exclusivity in certain circumstances, such as if a new way of delivering the active ingredient is proposed (for example, a tablet rather than a liquid) or a different disease or condition the drug can treat is identified. To get this approval, the drug company must conduct new clinical studies in humans.

Additional Exclusivities May Be Eligible

Pediatric: A brand-name drug for which the sponsor has done pediatric studies (in response to a written request from FDA) may be eligible for a **six-month** exclusivity, which is added on to any other exclusivities or patents for that drug.

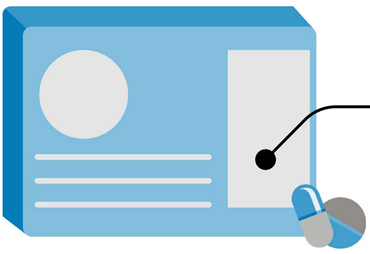
Antibiotic: Certain new antibiotic drugs for specific infectious diseases may be eligible for a **five-year** exclusivity, which is added on to any other exclusivities for that drug.

After exclusivities no longer block generic approval, generics can join the market if:

The generic drug applicant has shown that the product has met all FDA standards for approval.

Patent protection no longer blocks generic approval.

The first generic can also get an exclusivity.



The first generic drug applicant to submit a substantially complete generic application that includes a challenge to the brand-name drug's patents and that meets certain regulatory and legal requirements may be eligible for a **180-day** exclusivity.

Visit www.FDA.gov/GenericDrugs to learn more about marketing exclusivities.

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