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Drug Pricing and the Law: Regulatory Exclusivities

The Food and Drug Administration (FDA) generally must approve pharmaceutical products, such as drugs and biologics, before they can be marketed in the United States. To obtain approval of a new drug or biologic (i.e., the brand-name or reference product), the sponsor must submit to FDA data from clinical investigations demonstrating that the underlying product is safe and effective for its intended use. Conversely, a follow-on product, such as a generic drug or biosimilar, via an abbreviated process by relying upon the data generated to support approval of the reference product. In order to balance interests in competition with the countervailing interest in encouraging innovation, federal law establishes periods of regulatory exclusivity that limit FDA's ability to approve applications to market pharmaceutical products under certain circumstances.

There are two general categories of regulatory exclusivity: (1) data exclusivity, which precludes applicants from relying on the reference product's clinical data to demonstrate the safety and effectiveness of the follow-on product; and (2) marketing exclusivity, which precludes FDA from approving any other application for an identical or biosimilar product for the same use, even if the applicant has generated its own data. During a period of data exclusivity, a company could theoretically submit a full application with its own data for the same pharmaceutical product and use. As a practical matter, however, data exclusivity and marketing exclusivity may generate the same result due to the significant investments required to generate the necessary safety and effectiveness data.

This table describes the types of exclusivities available, their duration, criteria to obtain them, and the impact on FDA's ability to approve other applications. For more information, see CRS Report R45666, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress*, coordinated by Kevin J. Hickey.

Table 1. Regulatory Exclusivities for Pharmaceutical Products for Human Use

Type of Exclusivity	Length	Criteria	Effect
Drugs			
New Chemical Entity 21 U.S.C. §§ 355(c)(3)(E)(ii), 355(j)(5)(F)(ii), 355(u)	5 years; may be reduced to 4 years if abbreviated new drug application (ANDA) contains paragraph IV certification that a patent listed for the reference drug is invalid or not infringed by the generic product	Application for drug containing an active ingredient that has not been approved before; or application for a drug that contains as an active ingredient a single enantiomer (each of a pair of molecules that are mirror images of one another) that: (1) is contained in a previously approved racemic drug (a mixture of two enantiomers in equal amounts) but has not otherwise been approved as an active ingredient; (2) treats a therapeutic category that is different from that of the racemic drug or other approved enantiomer of the drug; and (3) does not rely on data contained in application for previously approved racemic drug and must include full reports of new clinical investigations	FDA cannot accept an abbreviated application for the same active ingredient that relies on the data in the reference drug application
Other New Product 21 U.S.C. §§ 355(c)(3)(E)(iii) & (iv), 355(j)(5)(F)(iii) & (iv)	3 years	Application for a change to an approved drug that contains at least one new clinical investigation that is "essential to the approval" of the application and is conducted or sponsored by the applicant	FDA cannot approve an application that relies on the data in the reference drug application for 3 years
First to File Paragraph IV 21 U.S.C. § 355(j)(5)(B)(iv)	180 days	First to file an ANDA with a paragraph IV certification that a patent listed for the reference drug is invalid or not infringed by the generic product	FDA cannot approve another ANDA for the same drug until 180 days after first commercial marketing of first filer

Type of Exclusivity	Length	Criteria	Effect
Competitive Generic Therapy 21 U.S.C. §§ 355(j)(5)(B)(v), 356h(b)	180 days	Designation as competitive generic therapy by FDA based on finding of "inadequate generic competition" (only one active approved drug); no unexpired patents or exclusivities for reference product	FDA cannot approve an ANDA for the same reference product until 180 days after first commercial marketing of the drug, *if* the first approved applicant has commenced commercial marketing
Biologics			
Biologic Reference Product 42 U.S.C. § 262(k)(7)(A) & (B)	4 and 12 years after date of first licensure	First licensure of a biological product that is: • not a supplemental application; • not a change resulting in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; and • not a modification to structure of product that does not result in a change in safety, purity, or potency	FDA cannot accept an abbreviated biologics license application referencing the product for first 4 years; FDA cannot approve an abbreviated biologics license application referencing the product for 12 years
Interchangeable Biologic 42 U.S.C. § 262(k)(6)	12-42 months, depending on timing of commercial marketing and patent litigation (see Effects column)	First interchangeable biologic approved for a reference product; interchangeable means the product is biosimilar to the reference product, produces the same clinical result in any given patient, and a patient can switch between the interchangeable and reference products over multiple doses without altering risk	FDA cannot determine another product is interchangeable with the reference product for any condition of use until the earliest of: (1) 1 year after commercial marketing; (2) 18 months after approval if not sued; or, (3) if sued, 18 months after decision or 42 months after approval
Other Purposes			
Pediatric Studies 21 U.S.C. § 355a(b) & (c) 42 U.S.C. § 242(m)	6 months	FDA requests that applicant conducts pediatric studies and such studies are completed	Extends other exclusivities by 6 months; delays approval for 6 months after listed patents expire
Orphan Drug 21 U.S.C. § 360cc	7 years	Designation by FDA as an orphan drug, which is a drug that treats a disease or condition that affects less than 200,000 people in the United States, or affects more than 200,000 people in the United States but there is no reasonable expectation that the cost of developing and making the drug would be recovered	FDA cannot approve another application for the same drug for the same disease or condition for 7 years, with limited exceptions
Qualified Infectious Disease Product 21 U.S.C. § 355f	5 years	Designation by FDA as a qualified infectious disease product (QIDP). QIDP means an antibacterial or antifungal drug intended to treat serious or life-threatening infections, including those caused by qualifying or resistant pathogens	Extends other exclusivities by 5 years

Source: CRS.

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