

Old and New Antibiotics

Eligibility for Hatch-Waxman Benefits and Other Exclusivities

Old Antibiotic Drugs							New Antibiotic Drugs
	Application Submitted under Section 507		Application Submitted under Section 505, before S.3560		Application Submitted under Section 505, after S.3560		
	Drug Approved under Section 507	Drug Not Approved under Section 507	Drug Approved under Section 507	Drug Not Approved under Section 507	Drug Approved under Section 507	Drug Not Approved under Section 507	
5-year NCE Exclusivity						X ²	X
3-year New Product Exclusivity					X ¹	X ^{1,2}	X
Orange Book Listings [includes Patent Certifications]	X ⁴		X ⁴		X	X ²	X
Patent Term Restoration						X ³	X

- 1 Product is eligible for 3-year data exclusivity only if condition of use was not approved before enactment of S.3560.
- 2 Product is eligible for data exclusivity and Orange Book listing if the applicant did not elect patent term restoration.
- 3 Product is eligible for patent term restoration if applicant did not elect data exclusivity.
- 4 Under the Transitional Rules, Orange Book Listings for patents issued as of the enactment date of S.3560 are available if the patents were listed within 60 days of the enactment of S.3560.