

Axinn Successfully Advocates for Preservation of 180-Day Marketing Exclusivity for Carvedilol ER

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ATTORNEYS

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PRACTICE AREAS

FDA

Axinn successfully advocated that FDA should preserve the 180-day marketing exclusivity period relating to a generic version of SmithKline's Coreg CR (carvedilol phosphate extended-release capsules) even though it took the ANDA applicant over 10 years to obtain tentative approval of its product. Through a series of correspondence submitted to FDA over the course of a number of years, Axinn successfully convinced FDA that the 180-day exclusivity period was not forfeited by Mutual Pharmaceutical Company (now Sun Pharma) because of a change in the approval requirements for the product. The Axinn team was led by Chad Landmon.

[Click here](#) to read FDA's decision and [here](#) to read press coverage on *FDA Law Blog*.