

Chad Landmon Discusses FDA's Letter Ruling Practice with The Pink Sheet

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ATTORNEYS

Landmon, Chad

PRACTICE AREAS

Intellectual Property

On November 3, 2008, The Pink Sheet reported on a recent letter ruling by FDA relating to the forfeiture of the generic exclusivity period by Hi-Tech relating to Cosopt (dorzolamide/timolol). Axinn's Chad Landmon commented on the ruling and discussed how FDA's practice of issuing its letter rulings on the eve of issuing approvals disadvantages the generic industry. "It's not fair to the generic companies who are investing a lot of resources into these products to have to wait until the absolute last minute" to discover the status of the exclusivity period, Landmon stated. "Both the first filer and later ANDA filers are disadvantaged by FDA's current practice. Moreover, district court judges are placed in the unenviable position of having to decide very complicated issues without sufficient time."