

U.S. District Court Grants Summary Judgment for Axinn's Client Zydus in FDA Case

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ATTORNEYS

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PRACTICE AREAS

FDA

Axinn attorneys, advocating on behalf of client Zydus Pharmaceuticals as a Defendant-Intervenor on the side of the U.S. Food and Drug Administration, won a summary judgment that affirms the FDA's authority and practice of allowing specific label carve-outs by ANDA generic drug makers. The U.S. District Court in Maryland rejected Otsuka's claim that the drug aripiprazole, which Otsuka markets under the name Abilify®, maintains market exclusivity from any generic use by virtue of its designation as an orphan drug for use in treating pediatric patients with Tourette's disorder.

The price competition created by the entry of generic versions of this prescription drug into the marketplace will benefit consumers who require aripiprazole to effectively treat a myriad of other medical conditions.

Partner Chad Landmon led the Axinn team.