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Eli Lilly and Company Notified of Abbreviated New Drug Application

Generic Manufacturer Follows Standard Industry Practice

Eli Lilly and Company has announced that a generic drug manufacturer has filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA) seeking permission to market a generic version of Zyprexa® (olanzapine) prior to the expiration of the Lilly U.S. patents for the product.

"In what has become an industrywide practice since the Waxman-Hatch Act of 1984, a generic drug manufacturer has filed an ANDA in an attempt to capture 'first-filer' status with the FDA on a patent-protected product by claiming the innovator's patent to be invalid," said Rebecca O. Kendall, Lilly senior vice president and general counsel. "Under the terms of that legislation, any generic manufacturer may make such a filing after the pioneer company has marketed its product for four years. Generic companies routinely do so in order to gain a possible 180-day period of market exclusivity over all other generic houses."

"We have strong patent protection well into the next decade for this product, including the compound patent that does not expire until 2011. We will take all steps necessary to defend our rights," Kendall continued.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.