Media Release
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Mayne announces tentative FDA approval of Fluconazole

Mayne Group Limited has announced that the US Food and Drug Administration (FDA) had granted tentative approval for the company's Abbreviated New Drug Application for fluconazole mini bags in 100ml and 200ml presentations. Fluconazole is used for the treatment of systemic fungal infections.

Patent protection for the raw material expires in early calendar 2004. Should Pfizer's branded product (Diflucan®) receive a 6-month paediatric extension, final approval and Mayne's launch date of fluconazole is expected to occur by August 2004.

The fluconazole mini bags are generic equivalents to Diflucan® which generates annual sales of approximately $US200 million.

Tentative approval from the FDA was achieved within 12 months of acquiring the rights to fluconazole from Baxter Healthcare Corporation.

Fluconazole will be a strong addition to Mayne's business in the US and further enhance the range of oncology and hospital-specific specialty products sold in the region.

Mayne Group Limited is listed on the Australian Stock Exchange and has businesses in pharmaceuticals (the manufacture of injectable and oral pharmaceuticals for distribution to more than 50 countries), health services (pathology, diagnostic imaging, medical centres, pharmacy services) and health-related consumer products.

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