

NDA 20-648/S-008

DIASTAT[®] ACUDIAL[™] RECTAL DELIVERY SYSTEM

(diazepam rectal gel)

RISK MANAGEMENT PROGRAM

2.2 Trade Distribution

Xcel (now Valeant Pharmaceuticals) had proposed a launch plan that allowed for potential overlap in the marketplace of the Diastat[®] AcuDial[™] and Diastat[®] Rectal Gel Delivery Systems for up to 6 months. In the 2 March 2005 Approvable Letter, the Agency stated concern regarding the potential for confusion in the marketplace. In response to this concern, Valeant intends to implement an inventory reduction plan and returns program with the goal of reducing wholesaler inventory to zero, which is estimated to result in a maximum of 1- to 2-day inventory in the retail channel at the time of launch. The trade distribution plan is summarized below.

Valeant uses three main wholesalers to distribute Diastat[®]: *Pharmacia, Amgen, and* a *third wholesaler*. Together, these wholesalers cover approximately 85% of the distribution of Diastat[®]. As of 31 March 2005, the wholesale channel had 5 weeks of inventory, taking all five product configurations (SKUs) into consideration, typical of prevailing inventory at any given time.

The major dispensing of Diastat[®] occurs at local pharmacies located in close proximity to prescribers' offices. Diastat[®] is generally not widely stocked at most chain drugstores due to cost, special storage requirements as a controlled substance, and infrequent

dispensing. The product tends to be ordered from wholesalers upon customer request. It is estimated that there was approximately 1 week or less of inventory in the local retail channel as of 31 March 2005.

Valeant intends to institute a wholesale inventory reduction period 5 weeks prior to the launch of AcuDial™. Wholesalers will be contacted directly by Valeant Customer Operations and instructed to reduce their inventories of Diastat® 5 mg, 10 mg, 15 mg, and 20 mg in preparation for the launch of Diastat® AcuDial™. As a standard procedure, Valeant reviews orders prior to releasing them for shipment. Orders submitted during the inventory reduction period for any of the four Diastat® SKUs that are to be discontinued will be cancelled.

During the fourth week, the Senior Director of Customer Operations from Valeant will contact the wholesalers directly via phone, and in addition, send a follow-up trade launch letter notifying them that Diastat® 5 mg, 10 mg, 15 mg, and 20 mg NDCs are being discontinued and being replaced with Diastat® AcuDial™, 10 mg and 20 mg.

By the end of the fifth week of the wholesale inventory reduction period, Valeant will begin shipping Diastat® AcuDial™ orders by next day air to wholesalers. The turnaround time to move the product from wholesalers to pharmacies is typically 24 hours or less. Pharmacies will be able to order Diastat® AcuDial™ through their wholesalers upon customer request and will receive the product within 24 hours. It is possible that some pharmacies may still have Diastat® on their shelves leading to a product overlap of a few days; however, this would be unlikely if wholesaler inventories are depleted and the fact that pharmacies do not routinely stock Diastat®.

As a precaution to remove any remaining Diastat® from the market place, the launch letter to pharmacists (see Section 2.3) will also include return instructions for the discontinued Diastat® 5 mg, 10 mg, 15 mg, and 20 mg. The letter will state that Valeant will accept returns of in-date Diastat® 5 mg, 10 mg, 15 mg, and 20 mg and instruct customers to return product to Valeant's returns processor,

At launch, Valeant will also ask wholesale customers to instruct their retail customers to return the discontinued Diastat® SKUs to

Valeant is informed of all returns by . Valeant Customer Operations Department will monitor all returns during this time interval to ensure program success.

By the end of the fifth week of the inventory reduction period, Valeant will begin shipping Diastat® AcuDial™ orders by next day air to wholesalers nationwide. Pharmacies will then be able to order and receive the new product from their wholesalers within 24 hours upon customer request.