Department of Health

MEDICINES CONTROL AGENCY

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M 2/12

26 November 2001

Dear Dr Taylor

4% DEXTROSE/0.18% SALINE AND HYPONATRAEMIA

Thank you for your helpful letter dated 23 October 2001. The MCA has conducted a review of 4% dextrose/0.18% saline and hyponatraemia in children. This has now been considered by the Working Group on Paediatric Medicines, a subgroup of CSM. The Working Group considered that although hyponatraemia is a risk in children during the use of 4% dextrose/0.18% saline, electrolyte imbalance is a risk with the use of all intravenous solutions. The Working Group noted that careful monitoring of children after surgery is crucial and in particular, care should be taken not to overload patients with intravenous fluids if they were oliguric as part of the normal response to surgery. The Working Group advised that there should be no amendments to product information.

With kind regards.

Yours sincerely

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Dr Katharine Cheng Medical Assessor Post Licensing Division Market Miner

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