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AJW/NK

13 March 1998

Dr M Pegg
Chairman
Ethics Committee
Royal Free Hospital

Dear Dr Pegg

Re: 22-98

1. Since this is an open labelled trial with no placebo group, no DDX is required. I have consulted with both the Dept of Health and their hand book on trials with respect to this.
2. We will change forthwith the definition of 60 mls in line with your recommendation of "6, 10ml spoons". Thank you very much for this helpful comment.
3. With respect to a control group, in this study we will not be using a control group. Any placebo effect would be expected to occur relatively early but not to be sustained over the 6-month period. In contrast, we do not expect a rapid effect from this drug; rather that its action will take place over a sustained period. Dr Berelowitz has extensive experience in therapeutic trials involving autistic children and should be able to distinguish, with confidence, the difference between placebo effect and the true benefit from the drug.

Thank you very much for your comments.

Yours sincerely

A handwritten signature in cursive script, appearing to read "J Walker-Smith".

J Walker-Smith
Professor of Paediatric Gastroenterology