MINISTRY OF HEALTH
MANATU HAUORA

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New Zealand
Phone (04) 496 2000
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Ref. No _____

7 December 2009

[redacted]

File Ref: TT50-8053

Dear [redacted]

Application for consent to distribute a new medicine under section 20 of the Medicines Act 1981 – Outcome of evaluation – Sativex oral spray – Received 7 January 2008

Evaluation of all information supplied in the application for consent to distribute the above product has been completed. Copies of the evaluation reports are enclosed.

Having reviewed the information supplied in your initial application and in your further responses, I am still not satisfied that I should consent to the distribution of the products because of the concerns about the safety, quality or efficacy of the medicines detailed in the attached evaluation report.

Therefore, as provided by section 22(2) of the Medicines Act 1981, I am referring your application to the Medicines Assessment Advisory Committee for consideration.

Yours sincerely

Anthony Hill
Deputy Director-General
Regulation and Governance Directorate