

Dr S Hutchings
CARDIFF UNIVERSITY
SOUTH EAST WALES TRIALS UNIT
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17/03/2011

Dear Dr S Hutchings

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our reference: 21323/0029/001-0001
Eudract Number: 2010-023476-23
Product: DURAPHAT DENTAL SUSPENSION 50MG/ML
Protocol number: SPON768-09

NOTICE OF ACCEPTANCE

I am writing to inform you that the Licensing Authority accepts your request for a clinical trial authorisation (CTA), received on 17/02/2011.

The authorisation is effective from the date of this letter although your trial may be suspended or terminated at any time by the Licensing Authority in accordance with regulation 31. You must notify the Licensing Authority within 90 days of the trial ending.

Finally, you are reminded that a favourable opinion from the Ethics Committee is also required before this trial can proceed.

Yours sincerely,

**Clinical Trials Unit
MHRA**