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SENDER TO KEEP
LIFT & PEEL
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Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Please Quote
Application No: PM 2010-02598
Clinical File No: 2011/000494

The Managing Director
Servier Laboratories (Australia) Pty Ltd
PO Box 196
Hawthorn Victoria 3122

Attention: Regulatory Affairs Manager

Dear Sir/Madam

Clinical Evaluation Report: Protos

With reference to your application to vary the conditions of registration Protos (strontium ranelate 2g), application no PM 2010-02598, a clinical evaluation report acceptable to this Office is now available. So that you may have the maximal time to consider this evaluation report prior to decision making, it is enclosed herewith. Please note that it does not necessarily represent the Delegate's proposed action.

Please review the report and if you consider that it contains errors of fact or major omissions, you should respond to the Delegate as soon as possible. Do not submit new data.

You are reminded that, in accordance with sections 3.6.1 and 3.11 of the Australian Guidelines for the Registration of Medicines (AGRM, "Sponsors should also notify the TGA of any serious adverse reactions which are observed for the first time or are inconsistent with that reported in the application. Sections 29A and 29B of the Therapeutic Goods Act 1989 also provide information on the responsibility of sponsors to submit any safety related information of public health significance during the course of the evaluation or thereafter.

Should you wish to arrange a meeting to discuss the evaluation report, please contact the undersigned without delay.

You now have the opportunity to respond formally to this report and amend the product information and consumer medicine information documents in accord with the report or state why not.

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Please identify clearly on any revised documents:

(i) changes to the documents which accord fully with the recommendations of t e evaluator

(ii) changes which are partially in accord with the evaluator's recommendations, together with reasons for not fully adopting them (eg reference to data, omissions or errors of fact in the evaluation)

(iii) reasons for contesting the evaluator's recommendations – do not supply new data

(iv) new amendments, analogous to safety related notifications, affecting safety matters

Thank you for your attention.

Yours faithfully

C. Chandrasekaran

for

Dr Neil Mitchell
Head
Clinical Evaluation Section 5
Office of Prescription Medicines

11 May 2011