Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

COMMONWEALTH OF AUSTRALIA

THERAPEUTIC GOODS ACT 1989

SECTION 14 AND 14A NOTICE

On 21 December 2012, the delegate of the Secretary of the Department of Health and Ageing for the purposes of sections 14 and 14A of the *Therapeutic Goods Act 1989* ("*the Act*") gave his consent to the following:

(a) the supply by Stryker Australia Pty Ltd, PO Box 970, ARTAMON NSW 1570 (the Company) of OP-1 IMPLANT eptotermin alfa (rch) 3.3 mg Powder for Suspension Vial AUST R 77949; AND

(b) for the above goods not to conform with the requirements of clauses 3(2) and 3(3) of the Therapeutic Goods Order No 69 - "General Requirements for Labels for Medicines".

Pursuant to section 15(1) of the Act, the consent given by the delegate of the Secretary as described above is subject to the following conditions:

- The vial may not be over-stickered as it is terminally sterilised in the blister pack by irradiation
- The blister-packed vials are supplied in Australian approved packaging
- The label on the blister pack complies with TGO 69
- The carton includes an insert explaining the product is the same but bears a different label
- This exemption applies only to one batch (AH 11A212)

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