health

Department:
Health
REPUBLIC OF SOUTH AFRICA

MEDICINES CONTROL COUNCIL
The Registrar of Medicines, Private Bag X828, PRETORIA, 0001
Tel (012) 312 0000 Fax (012) 312 3105
Tel: 012-3120230 *Inquiries:* Dr J Gouws
Fax: 012-3123165 *Reference:* B1/z C38 12.02

Regualtory Affairs Pharmacist
Astellas Pharma (Pty) Ltd
Gillooly's View Office Park Block F
5 Osborne Lane
Bedfordview
2007

Tel: 011 615 9133
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Attention: Elizabeth Cloete

12.02 EXCLUSION OF A MEDICINE, IN TERMS OF SECTION 36 OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965), FROM THE OPERATION OF CERTAIN PROVISIONS OF THE ACT:

REGULATION 8(1): LABELLING OF MEDICINES INTENDED FOR ADMINISTRATION TOHUMANS (Bilingualism of the immediate and outer container, schedule and registration number on outer container)
REGULATION 9(1): PAKAGE INSERTS FOR MEDICINES FOR HUMAN USE (Bilingualism of the package insert)
REGULATION 10(1): PATIENT INFORMATION LEAFLET (bilingualism of the patient information leaflet)
AND IN TERMS OF REGULATION 8(3) TO ALLOW FOR THE INCLUSION OF ADDITIONAL INFORMATION ON THE LABEL OF THE MEDICINE

PROGRAF CONCERNTRATE FOR SOLUTION FOR INFUSION 5mg/ml **32/34/0561**

Your letter dated 30 July 2009 refers. Kindly note that your request for exemption in terms of Section 36 of the Medicines and Related Substances Act, 1965 has been tabled at the Medicines Control Council meeting of 27 January 2010.

MOTION 12.02

In terms of Section 36 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) Council resolves to RECOMMEND to the Minister of Health that the medicine(s):

Name of Medicine	Registration nr	Registration Certificate Holder
Prograf	**32/34/0561**	**Astellas Pharma (Pty) Ltd**

be exempted from the requirements of:

Regulation 8: labelling of medicines intended for human administration in so far as bilingualism, inclusion of the scheduling status on the outer container and registration number;
Regulation 9: package inserts for medicines for human use in so far as bilingualism, scheduling status, pharmacological classification, registration number, name and address of the Holder of Certificate of Registration;
Regulation 10: Patient information leaflet in so far as bilingualism, scheduling status, registration number, name and address of the Holder of Certificate of Registration; and
Regulation 8(3): to allow for the inclusion of additional information on the label of the medicine which will include the product UK marketing authorisation number.

Yours faithfully

REGISTRAR OF MEDICINES
DATE: 8/2/2010