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Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Clinical File No: 2011/010251
PI/CMI File No: 2011/006238
Sub No: PM-2011-01912-3/5

Comment [e1]: f. 5, 2011/010251

The Managing Director
Eli Lilly Australia Pty Limited
112 Wharf Road
WEST RYDE NSW 2114

Comment [e2]: f. 4, 2011/010251

ATTENTION: [redacted]

Comment [e3]: f. 2, 2011/010251

Re: Safety Related Notification for:

Product/s:

- **76462** - ACTOS Pioglitazone 15mg (as hydrochloride) tablet - uncoated blister pack
- **76463** - ACTOS Pioglitazone 30mg (as hydrochloride) tablet - uncoated blister pack
- **76464** - ACTOS Pioglitazone 45mg (as hydrochloride) tablet - uncoated blister pack

Under Section 9D(2) of the Therapeutic Goods Act 1989

Your notification dated 23 June 2011 for safety related changes made to the product information for the above has been received. Your assurance that no other changes have been made to the product information document has been noted.

Comment [e4]: f. 2, 2011/010251

Comment [e5]: f. 2, 2011/010251

Your safety related changes as described in your letter of 23 June 2011 are acceptable under Section 9D(2) of the Therapeutic Goods Act 1989.

Comment [e6]: f. 2, 2011/010251

You are reminded that there is a continuing obligation to ensure that at all times the patient information document (Consumer Medicine Information - CMI - formerly CPI) complies with the statutory requirements. Following amendment of the Product Information, any changes needed to the CMI to ensure consistency with the Product Information must be made within ONE month of the approval or notification of the change to the Product Information. In the case of changes relating to the safety or safe use of the product, more rapid change of the CMI may be warranted.

Comment [e7]: f. 4, 42, 2011/010251 Date: 11-01911_MS_V1_CL.

For the products acknowledged in this submission, the:

- Product Information (PI) document(s) acknowledged by the TGA must be lodged with the TGA **within 2 weeks** of the date of registration of the product/s or date of acknowledgement of the variation(s), and
- related Consumer Medicine Information (CMI) document(s) must be lodged with the TGA:
- for new product/s - prior to supply of the product/s

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
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TGA Health Safety Regulation

[redacted]

- for variations to existing products - **within 2 weeks** of the date of acknowledgement of the variation.

The documents must be lodged in the TGA eBusiness Services system (eBS) - information on how to lodge these documents is available at www.ebs.tga.gov.au

Note that documents lodged must be in text PDF format – please be aware that scanned PDF documents will not be accepted by the system.

If you have two Product Information documents, one for all marketed products and the other for all registered products, then BOTH DOCUMENTS must be forwarded to the TGA.

Please Note: The Product Information Document **MUST** retain the current date of approval of the Product Information and also include the **notification date** of the **LATEST** safety related change.

Yours sincerely,

Nasis Ellis
Office of Medicines Authorisation
Prescription Medicines Clinical Unit 5
TGA
Tel: 02 6232 8344 Fax: 02 62328344

6 July 2011