TGA Therapeutic Goods Administration
PO Box 100, Woden, ACT 2606, Australia
☐ Woden Telephone: (06) 289 1555. Fax: (06) 289 8709
☐ Mawson Telephone: (06) 286 0222. Fax: (06) 286 1386

COMMONWEALTH DEPARTMENT OF HEALTH, HOUSING AND COMMUNITY SERVICES

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File No. 93/16630
Appl No. 91/156/2
Eval No. a030

The Managing Director
Marion Merrell Dow Australia Pty Ltd
Locked Mail Bag 30
Frenchs Forest NSW 2086

Attention: [redacted]
Scientific Affairs Associate

Dear Sir

I refer to your letters of 12 March 1991, 29 July 1991, 12 September 1991, 1 December 1992, 29 April 1993 and 29 July 1993 concerning the application for registration of teicoplanin "Targocid" powder for injection (100, 200 and 400 mg strengths) presented in glass vials with ampoules of water for injection included under the provisions of the Therapeutic Goods Act 1984.

Your additional data and responses to outstanding matters of chemistry and quality control have now been evaluated and you are required to provide the following further information under Section 31(1) of the Act to allow the Secretary to make a decision regarding your application. ~~Your response should be provided within one month of the date of this letter.~~

The numbering of the following matters has been retained from those raised in TGA's letter of 10 June 1993.

SAFETY MATTERS

13.1 It is noted that the present General LAL Test method and the procedure for sample preparation for Water for Injection for the Bacterial Endotoxin Test are currently being reviewed and updated by the company , a process which should be completed by the end of September.

Any proposed alterations to Bacterial Endotoxin Test methods are to be forwarded to TGA.

a. Please provide the revised versions of methods, General LAL Test Method (B267000) and procedure for sample preparation for Water for Injection for the Bacterial Endotoxin Test (B269800), when available.

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The General LAL Test method (B267000) needs to include:
i) Methods for
. calibration of a CSE with the RSE;
. confirmation of the labelled LAL reagent sensitivity;
. inhibition/enhancement test with separate CSE standard curves one in water and the other in product;
. test procedure with one dilution of product and a CSE standard curve in water;
ii) Maximum Valid Dilution (MVD) formula; and
iii) Confirmation that the reagents are approved by the FDA.

b. When the LAL method for the Teicoplanin powder is available the MVD calculation and the following results, specific for the Teicoplanin powder, are to be forwarded to TGA:

i) Inhibition/enhancement test results for 3 batches showing the non-inhibitory concentration of the product; and

ii) Routine Test results for 3 batches having a CSE standard curve with each test and stating the routine test dilution for the product.

OTHER MATTERS

15. You are required to provide completed 'DESCRIPTION OF GOODS FOR ACCEPTABILITY TO SUPPLY' forms to enable the Secretary to make a decision regarding your registration application. A blank form is enclosed for your reference.

Your response should be provided within ~~one month~~ 14 days of the date of this letter.

The TGA has allowed what it believes to be an adequate timeframe for your response. However, if you believe that the timeframe is inadequate, please raise your concern with the undersigned at the time the request is received, with the option of recourse to the SAC if you are still aggrieved and if the grounds for your concern are technical in nature. Requests for an extension of time will only be entertained on the basis of extenuating circumstances and will therefore need to be supported by a soundly based case.

Please note that, in accordance with Regulation 16A of the Therapeutic Goods Regulations, the date by which your application must be decided by the Secretary has been extended due to this request for information. Please also note that partial responses will not restart the clock.

Please address your response, quoting the abovementioned file and control numbers, to:

Section 31 Officer
(Attn: [redacted])
Application Entry Cell
Drug Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Yours sincerely

[redacted]

[redacted] 10/9/93.
Chief Scientist
Antibiotics Section
Therapeutic Goods Administration Laboratories
Delegate of the Secretary
([redacted])

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VERIFIED WTA: –
C/No: 91-156-2 Date: 13.9.93