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PARTNERS IN GLOBAL HEALTHCARE

16 August 2013

Dr. G. N. Singh,
Drugs Controller General (I)
Central Drugs Standard Control Organization,
FDA Bhavan, New Delhi

Dear Sir,

This has reference to the Government of India notification GSR 520(E) dates 31st July 2013, that revokes the suspension placed on Pioglitazone Formulations subject to printing of the prescribed warning on the package insert and promotional literature as an advice for the healthcare professionals. We thank you and the Ministry of Health & Family Welfare for the prompt and positive action as requested by the industry

It is understood that the requirement of printing the warning on the package insert is being interpreted differently by trade and regulators in some of the states leading to stoppage of sales in these states. For example, the stockist association has interpreted this notification as a requirement to print the information on the box of the product in addition to printing it on the package insert. In some other cases, it is insisted that each strip should have this warning which is neither required nor it is possible to print.

These views are erroneous and arise possibly out of the misinterpretation of the term 'Box warning' included in the notification. The term box warning is used as an adjective and is meant to indicate that the information that follows the statement has to be placed in an outline to highlight to the prescriber and not literally to print it on the box. This term is described in the enclosed US FDA guidance document (refer to page 11).

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Such misinterpretations by the Trade and Regulators have far reaching effects in as much as such additional labeling, when not mandated, may lead to non compliance with the labeling requirements besides adding to the confusion.

In view of this, we request you to kindly instruct the Trade and the State Regulatory Authorities to allow sale of Pioglitazone formulations if a package insert is placed in each box as required by the notification and not to insist that the warning be printed on the box or on the strip which is practically not possible.

Thanks & Regards,

M U Doshi
President

Encl: US FDA Guidance Document