[FDA MEMORANDUM CIRCULAR NO. 2010-020, October 18, 2010]

SUSPENSION OF MANUFACTURE, IMPORTATION, DISTRIBUTION, AND/OR MARKETING OF ALL ROSIGLITAZONE-CONTAINING PRODUCTS

The Food and Drug Administration is informing all concerned of its decision to suspend the manufacture, importation, distribution, or marketing of all Rosiglitazone-containing products effective immediately. The EMA suspended the marketing of the above product and although the US FDA decided to keep it in the market under severely restricted use, it may be used only by patients who do not respond to other medications. The FDA's decision was reached after an evaluation on the information gathered relative to the assessment of the risk-benefit ratio of Rosiglitazone-containing products. It was concluded that there is an increased cardiovascular risk that outweighed its benefit for the management of diabetes. Also, there are other drugs with similar benefit that may be used that are not associated with increased cardiovascular risk.

Accordingly, all concerned establishments producing or distributing the subject product are enjoined to suspend from further manufacturing, importing, distributing, selling and/or offering for sale the same until further notice from this Office. Evaluation of applications for registration covering Rosiglitazone-containing products, as well as, approval of those already evaluated, if any, are likewise suspended.

Finally, all concerned are advised to immediately report to this Office any information of a possible adverse effect associated with the use of the above product and the manufacturers and/or the importers shall set up the necessary hotlines to handle inquiries concerning this suspension.

This is for immediate compliance from notice hereof.

Adopted: 18 October 2010

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