[FDA MEMORANDUM CIRCULAR NO. 2010-019, October 18, 2010]

SUSPENSION OF MANUFACTURE, IMPORTATION, DISTRIBUTION, AND/OR MARKETING OF SIBUTRAMINE PRODUCTS

The Food and Drug Administration is informing all concerned of its decision to suspend the manufacture, importation, distribution, or marketing of all Sibutramine (single component and Sibutramine containing products) effective immediately. The decision was reached after evaluation of the information gathered relative to the assessment of the risk-benefit ratio of Sibutramine products. It was concluded that unnecessary cardiovascular risks to patients outweighed patients. Other Drug Regulatory Authorities have already recommended against the continued use of Sibutramine or have decided to suspend the marketing of the same.

Accordingly, all concerned establishments producing or distributing the subject product are enjoined from further notice from this Office. Evaluation of applications for registration covering Sibutramine 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 adverse effects associated with the use of the above product and to 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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Acting Director IV