[FDA CIRCULAR NO. 2013-028, December 13, 2013]

SUSPENSION OF MANUFACTURE, IMPORTATION, DISTRIBUTION, AND/OR MARKETING OF KETOCONAZOLE ORAL PRODUCTS

The Food and Drug Administration is informing all concerned of its decision to suspend the marketing authorizations of oral ketoconazole-containing products effective immediately. The decision was finalized after deliberation on the negative risk-benefit assessment for ketoconazole-containing products. It was concluded that risk of serious liver injury outweighs the benefits in treating fungal infections.

Accordingly, all concerned establishments are hereby ordered to immediately cease and desist from further manufacturing, importing, distributing, selling or offer for sale of oral ketoconazole products. Evaluation of applications for registration covering oral ketoconazole products, as well as approval of those already evaluated, are likewise suspended. Doctors should discontinue prescribing oral ketoconazole products and recommend an appropriate alternative for fungal infection. Patients currently on oral ketoconazole should consult their doctor for alternative treatment.

Finally, all concerned are advised to immediately report to this Office any information of adverse effects associated with the use of oral ketoconazole products.

For more information and inquiries, please e-mail us at info@fda.gov.ph. Any report about establishments dealing illegally with sale or offer for sale of unregistered health products should be reported immediately to FDA at report@fda.gov.ph.

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