



Republic of the Philippines  
Department of Health  
**BUREAU OF FOOD AND DRUGS**  
Civic Drive, Filinvest Corporate City  
Alabang, Muntinlupa City

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BUREAU CIRCULAR  
No. 05 s 2005

TO : ALL CONCERNED DRUG MANUFACTURERS AND  
DISTRIBUTORS

SUBJECT : **Black box warning for all antidepressant drugs**

In view of the increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with antidepressants the Bureau of Food and Drugs mandates all manufacturers and distributors to revise the labeling for all antidepressant and include a 'black box' warning regarding the increased risk of suicidal in children and adolescent. The Bureau of Food and Drugs in requesting all companies concerned to add the 'black box' at the beginning of package inserts and will state the following:

'Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders' and those considering use of these agents "must balance risk with the clinical need"

For your information and guidance.

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Director