

TAHEEBO/PAU D & ARCO/LAPACHO

BFAD CIRCULAR NO. 17, S. 2004, October 28, 2004

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For the information and guidance of BFAD staff, clients and consumers, this Bureau Circular is issued regarding Taheebo/ Pau d 'arco / Lapacho.

Taheebo is also known as Pau d 'arco or Lapacho. It is a herbal ingredient from the inner bark of *Tabebuia impetiginosa*. The use of taheebo has been shown to increase bleeding tendencies as measured by prolonged prothrombine time. Such adverse event is magnified and enhanced with concomitant intake of aspirin, ticlopidine (Ticlid), warfarin (Coumadin), heparin, Ginkgo biloba and ginseng. Although animal studies have demonstrated Taheebo's relative safety with the Acute Toxicity Testing using Lethal Dose 50 (LD50), still there were reports of liver and kidney damages in humans at very high doses. Low doses were also shown to cause nausea, vomiting, diarrhea and anemia.

In relation to the aforementioned, the Bureau of Food and Drugs shall require companies importing, selling and distributing taheebo-containing products to amend their product labels by incorporating the following:

1. "This product is not intended to diagnose, treat, cure, and prevent disease"
2. "Maximum daily intake up to 3 cups per day only"
3. "should not be taken with aspirin, ticlopidine, ginkgo biloba, ginseng, warfarin & heparin"
4. "should not be taken by pregnant or breast-feeding mother"
5. "should not be taken at least one week before contemplated operation"
6. Stop intake of this product in the event of nausea, vomiting, diarrhea, skin pallor, bruises and nose bleeding.

Noncompliance with these recommendations shall be a ground for cancellation of the Certificate of Product Registration (CPR).

Adopted: 28 Oct. 2004

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