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31 January 2001

The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200C. Street S.W. Washington, DC 20204 USA

Dear Sir/Madam

This is a notification pursuant to 21 U.S.C. 343(r)(6) that MediHerb of Warwick, Qld, 4370, Australia is making statements about a dietary supplement.

Kava Kava 1:2 is the name of the product that is the subject of this notification.

Kava Kava 1:2 contains the herb Kava Kava. The statements being made are as follows:

- ease the effects of temporary stress
- promote relaxation and sleep, and
- promote relaxation in both smooth and skeletal muscle tissue.

The information contained herein is accurate and MediHerb has substantiation that the statements are truthful and not misleading.

Yours sincerely

Research Manager

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