



**Thursday
Plantation**

Health from Nature

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Laboratories Limited**
ABN 17 002 833 141

3 March 2003

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Mr Daniel P. Keravich
Regulatory Projects Manager
Division of Over-the-Counter Drug Products
Document Control Room HFD-560
FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
ROCKVILLE, MARYLAND 20857

Fax: 0015-1-301-827-6870

Dear Mr Keravich,

**Re.: Time and Extent Application for Tea Tree Oil as an Antiseptic Active Ingredient
for OTC Unrestricted Distribution
OTC files Track ID # 3308
(Refer Docket Numbers: 78N-183H, 75N-183F, 96N-0277)**

I am referring to your correspondence dated February 6, 2003 to our Chairman, Mr Christopher Dean.

As there were several citizen petitions submitted to the FDA over a number of years concerning Australian tea tree oil, we require clarification from you as to the specific citizen petition and Docket Number referred to by your review division for which the additional information listed in your correspondence is requested. You have indicated that certain uses for tea tree oil might be under consideration as part of ongoing rulemakings and that, for example, tea tree oil is currently being review as an active ingredient for the first aid antiseptic drug monograph (final monograph). It is for these reasons and to eliminate any further confusion that we would appreciate it if you would provide us with the title of the CP referred to in your correspondence by your review division with regard to additional TEA information, the CP's original submission date and Docket Number.

Our fax number is +61-2-6686-7485. I can also be contacted at my e-mail address riedl@thursdayplantation.com

Thanking you in anticipation of your help in this matter.

Yours sincerely

Robert Riedl
Technical Manager
Regulatory Affairs

cc. Christopher Dean, Chairman

75N-183F

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