



**Thursdays
Plantation**

Health from Nature

**Thursdays Plantation
Laboratories Limited**
ABN 17 002 833 141

5722 '01 MAY 21 P2:16

May 16, 2001

Food and Drug Administration
5630 Fishers Lane Rm. 1061
Rockville, MD 20852

Dear Sir/Madam:

We would like to inquire regarding our label exemption application dated March 23, 2001, for the following over-the-counter drug product:

Thursdays Plantation 100% Pure Tea Tree Oil
Sizes: 1/3 fl oz and 2 fl oz

Should you have any questions or need more information, please contact me at 559-346-0233.

Your kind consideration and immediate action are greatly appreciated.

Sincerely Yours,

THURSDAY PLANTATION LABORATORIES, LTD

Norma Daliva-Banks
Regulatory Affairs

Attachment: copies of March 23, 2001 correspondence

98N-0337

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**Thursday
Plantation**

Health from Plants

**Thursday Plantation
Laboratories Limited**
ACN 002 833 141

23 March 2001

Food and Drug Administration
5830 Fishers Lane r. 1061
Rockville, MD 20852
USA

Dear Sir/Madam,

**Re: Thursdays Plantation Laboratories Ltd.
Thursdays Plantation 100% Pure Tea Tree Oil
Size: 1/3 fl.oz**

We would like to request exemption from your requirement of 21CFR201.66 based on the following circumstances presented. It is impracticable due to:

1. The label size is too small to fit bar lines and all the wording in the font size required.

Please find enclosed our proposed label artwork for this product.

Should you have any questions and need more information, please contact our regulatory consultant, Mrs Norma Daliva-Banks at 559-346-0233, California, USA.

Your kind consideration and immediate action are greatly appreciated.

Thanking you.

Yours sincerely

**Robert Riedi
Technical Manager
Regulatory Affairs**

Pacific Highway Ballina NSW 2478 Australia
Telephone: (02) 6606 7273 Facsimile: (02) 6606 7485 International Fax +61 2 6606 7485
www.thursdaysplantation.com email: teetree@thursdaysplantation.com



**Quality
Endorsed
Company**
ISO 9001 Certified
Standard Australia
10/01/00



**Thursday
Plantation**

Health from Plants

**Thursday Plantation
Laboratories Limited**

ACN 002 833 141

23 March 2001

Food and Drug Administration
5630 Fishers Lane rm. 1061
Rockville, MD 20852
USA

Dear Sir/Madam,

**Re.: Thursday Plantation Laboratories Ltd.
Thursday Plantation 100% Pure Tea Tree Oil
Size: 2 fl.oz**

We would like to request exemption from your requirement of 21CFR201.66 based on the following circumstances presented. It is impracticable due to:

1. The label size is too small to fit bar lines and all the wording in the font size required;
2. Should the font size be decreased, the letters bleed slightly which may cause deterioration of the text legibility.

Please find enclosed our proposed label artwork for this product.

Should you have any questions and need more information, please contact our regulatory consultant, Mrs Norma Daliva-Banks at 559-346-0233, California, USA.

Your kind consideration and immediate action are greatly appreciated.

Thanking you,

Yours sincerely

**Robert Riedl
Technical Manager
Regulatory Affairs**

Pacific Highway Ballina NSW 2478 Australia
Telephone: (02) 6686 7273 Facsimile: (02) 6686 7485 International Fax +61 2 6686 7485
www.thursdayplantation.com email: teacree@thursdayplantation.com



**Quality
Endorsed
Company**
ISO 9001 Lic5498
Dandenong Australia
October 2000

NORMA D. DALIVA-BANKS
C/O GENERITECH CORP.
4967 E. LANSING WAY
FRESNO, CA 93727



FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE RM. 1061
ROCKVILLE, MD 20852

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