RURAL INDUSTRIES RESEARCH
& DEVELOPMENT CORPORATION

Ref: R02/196

31 July 2002

Mr Charles Ganley
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857
USA

Dr Walter Ellenberg
Regulatory Health Project Manager
Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857
USA

Dear Mr Ganley and Dr Ellenberg

Re: Docket numbers: 78N-183H, 75N-183F and 96N-0277

I would like to thank you for the extension to 21st August 2002 for the industry to complete a TEA. However, as you sent it on 20th June by sea mail (and to the wrong person- Tony Byrne), I did not receive it until 3rd July the day before I went on 2 weeks leave. I dispatched it to industry who met late last week.

I have been asked to request a further 120 day extension, which will allow the industry time to finalise the data in the necessary form required to submit it to you. Please confirm this extension as soon as possible.

We will also be unable to make clear progress until you can provide an answer to the questions that we asked in our previous letter. These are repeated below.

- Our records do not conform with either of the docket numbers supplied in your letter dated 19th April 2002 or that of 20th June 2002 (96N-0277). The industry is interested in a response from you to our submission in 1998 which is numbered docket number 75N-183F and it would appear that there may be a typographic error in the letter supplied by the FDA (on 19th April 2002) which refers to a submission in 1995 with the Docket No 78N- 183H. As there were four separate submissions submitted over a number of years we need to confirm whether your letter applies to all of these submissions or just the one in particular (20th January 1995) of which we have no record.

- In your letter you state that there is no market history of Tea Tree Oil in the USA. Tea Tree Oil has in fact been sold in many countries for many years, including

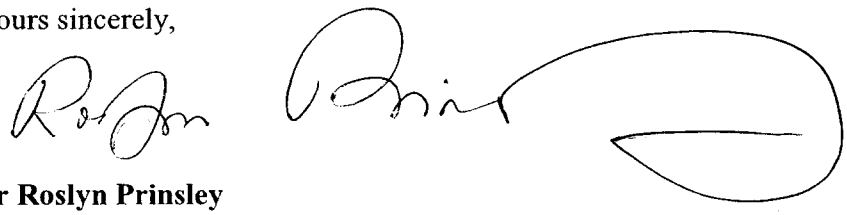
since at least 1962 in the USA. The industry has available statistical data confirming the quantified extent of marketing of Tea Tree Oil as an antiseptic in a number of countries around the world. Please advise if this data is required to support any of the Citizen Petitions which have been submitted on behalf of ATTIA, or is this data only required for the particular Citizen Petition which is referred to in your letter (for which we have no corresponding reference number)?

I would like to reiterate that the Australian Tea Tree Industry Association is still very interested in the outcome of its submissions, and I am requesting sufficient time on their behalf to complete whatever is required once this has been clarified. Indeed, the Australian Therapeutic Goods Administration (TGA) recognises Australian Tea Tree Oil as a safe and effective natural antiseptic and it is registered in Australia for this purpose. I attach a certificate of Pharmaceutical Product supplied by the as evidence for safe marketing of this product. There have been many millions of units of 100% Pure Tea Tree Oil sold as a general topical antiseptic over many years in many countries around the world and we are anxious to make sure that this product continues to be available in the USA.

In addition, I would like to remind you that it has now been nearly four years since our submission in 1998 and I am unclear as to whether a response will be forthcoming in addition to these two letters.

I particularly look forward to your early response to this letter (to me and not to Tony Byrne) and would appreciate it if you also send it by email to Roslyn.Prinsley@rirdc.gov.au .

Yours sincerely,



Dr Roslyn Prinsley
General Manager, Research

CC: Pat Bolster
Richard Davis
Christopher Dean
David Nicholson
Sally Prescott

Encl: Certificate

TGA THERAPEUTIC GOODS ADMINISTRATION

Certificate of a Pharmaceutical Product[1]

This certificate conforms to the format recommended by the World Health Organization. For explanatory notes see page 2.

Exporting (certifying) country: **Australia**
Importing (requesting) country: **United States of America**

1. **Name and dosage form of product:**
THURSDAY PLANTATION 100% PURE TEA TREE OIL ANTISEPTIC lotion bottle

Certificate No. 02/1022

1.1 **Active ingredient(s)[2] and amount(s) per unit dose[3] (if applicable):**
(for complete composition including excipients see Schedule 1, attached to this Certificate)

1.2 **Is this product licensed to be placed on the market for use in the exporting country?[4]** YES

1.3 **Is this product on the market in the exporting country?** YES

TGA comments:	**This product has been approved by the TGA and is permitted to be supplied in Australia**

Sponsor's comments:	**Not applicable**

2.

Listing/Registration No: AUST R 15674 12 September 1991
Name and address of applicant: Thursday Plantation Laboratories Limited, Pacific Highway, Ballina, New South Wales 2478, Australia
Status of applicant[5] (categories as defined in note 5): (a) **For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:[6]**
Is officially approved product information, complete and consonant with the licence, attached? Not provided

3. **Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?[7]** YES, IF APPLICABLE*
*For manufacturing steps carried out in Australia. For overseas manufacturers evidence of satisfactory GMP compliance has been supplied.

3.1 **Periodicity of routine inspections (years):** NOT LESS THAN EVERY TWO YEARS

3.2 **Has the manufacture of this type of dosage form been inspected?** YES

3.3 **Do the facilities and operations conform to GMP as recommended by the World Health Organization?[7,8]** YES

4. **Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?** YES

AUSTRALIA
Department of Health and Ageing

Certifying authority:

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia

Telephone: +61 2 6270 4333
Facsimile: +61 2 6270 4336

Name of authorised person: Mohammed Ali

Signature: _____

Date: 19/06/02

No. of Schedules attached to this Certificate: 02

Certificate No. 02/1022

Authentication

Explanatory Notes

1. This certificate, which is in the format recommended by the WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only, since manufacturing arrangements and approved information for different dosage forms and strengths can vary.
2. Use, whenever possible, international nonproprietary names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or appended.
4. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is entered into the product licence.
5. Specify whether the person responsible for placing the product on the market:
   (a) manufactures the dosage form;
   (b) packages and/or labels a dosage form manufactured by an independent company; or
   (c) is involved in none of the above.
6. This information can only be provided with the consent of the product licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
7. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
8. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the report of the Thirty-second Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No 823, 1992. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization and are published in the WHO Technical Report Series.

AUSTRALIA

Department of
Health and Ageing

Summary of the Australian regulatory controls over drug products for human use

02 / 1022

The Commonwealth *Therapeutic Goods Act 1989* ("the Act") establishes and maintains a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia. Therapeutic goods are products used in the prevention, diagnosis, cure or alleviation of a disease, ailment, defect or injury and include those goods which are likely to be taken to be for therapeutic use because of the way they are presented or advertised. Therapeutic goods which have been accepted by the Therapeutic Goods Administration are included in the Australian Register of Therapeutic Goods (ARTG), which is a computer database holding details of therapeutic goods supplied in, or exported from, Australia. Some therapeutic goods are subject to the Act but exempt from listing on the ARTG.
There are three categories of medicinal products within the ARTG:

1 Listed medicines (including complementary medicines) approved for supply in Australia
These are therapeutic goods which are formulated from a restricted list of active ingredients for which there are minimal safety concerns. They are indicated for self-limiting conditions and are of acceptable presentation (including labelling). These products, containing active substances whose quality and safety have been accepted, include vitamin & mineral supplements, most herbal medicines, homoeopathic products and sunscreens. While stability data is required to be available, or being generated to support the claimed shelf life, this is not verified by the TGA. Sponsors are also required to hold evidence to support any label claims, however this evidence is not evaluated by the TGA prior to entry in the ARTG. Once listed in the ARTG, these goods may then also be exported without further regulation. Exporters may request the TGA to issue Certificates of Pharmaceutical Product or Certificates of Listed Product for these products (see note below).

2 Registered medicines
These are therapeutic goods other than those that may be listed and are evaluated with regard to their quality, safety *and efficacy* before being approved for supply. They include the onventional pharmaceutical products, traditional remedies which include animal parts and medicines for the treatment of more serious diseases. Once included in the ARTG, these goods may also be exported without further regulation. Exporters may request the TGA to issue Certificates of Pharmaceutical Product for these products.

3 Medicines intended solely for export
These are goods that may be manufactured to satisfy an overseas supplier's requirement. They are subject to similar standards as apply to other listed therapeutic goods that are supplied in Australia . Where the product is exported in the final packaging, the TGA does not assess label indications or whether label warning statements required for approval in Australia have been included. Sponsors are required to declare that the label will meet the requirements of the importing country. Product labels cannot contain information which is false or misleading. Exporters may request the TGA to issue Certificates of Pharmaceutical Product for these products.

Where an application to register or list a product has been rejected for supply in Australia for safety or quality reasons and it is proposed to export such a product, or there are other concerns with a product manufactured solely for export, the TGA will contact the importing regulatory authority to confirm there is no objection to the export of the goods.

Export Certificates
The TGA provides two types of export certificates, a Certificate of Pharmaceutical Product (CPP) and a Certificate of Listed Product (CLP). While both certificates are based on principles of the WHO Scheme for export certification, only the CPP is formally issued under this scheme. The CLP is a modified certificate provided only for medicines listed for supply in Australia. While a CPP can be provided for both listed and registered medicines, a CLP can only be provided for listed medicines which may be supplied in Australia.

Standards - All therapeutic goods that are exported from, imported into or supplied in Australia must comply with internationally recognised standards that are of a comparable standard to those that apply to such goods in Australia. The only exception is that labelling of goods manufactured solely for export does not need to conform to labelling requirements applicable to goods supplied in Australia.

Licensing of manufacturers - The Act provides for the licensing in Australia of manufacturers of therapeutic goods for human use. In order to obtain a licence a manufacturer is inspected to confirm compliance with the codes of good manufacturing practice. Overseas manufacturers must be able to demonstrate that their standards of manufacture and quality assurance are equivalent to that of Australian manufacturers.

This page is intended as a summary of the main features of the national regulatory scheme. Specific queries or requests for clarification should be directed to:
The Export Medicines Unit, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606, Australia.

Thursday Plantation
Health from Nature

Thursday Plantation
Laboratories Limited
ABN 17 002 833 141

Schedule 1 to Certificate of a Pharmaceutical

Product No. 02/1022

Formulation Details:

Thursday Plantation 100% Pure Tea Tree Oil

Active Ingredients

Melaleuca Oil	1 mL/mL

I, Robert Riedl, Technical Manager – Regulatory Affairs of Thursday Plantation Laboratories Ltd., declare that the information given in this schedule is current and correct.

Robert Riedl

4 June 02
Date

Department of Health and Ageing

Quality System
Quality Endorsed Company
ISO 9001 LIC5496
Standards

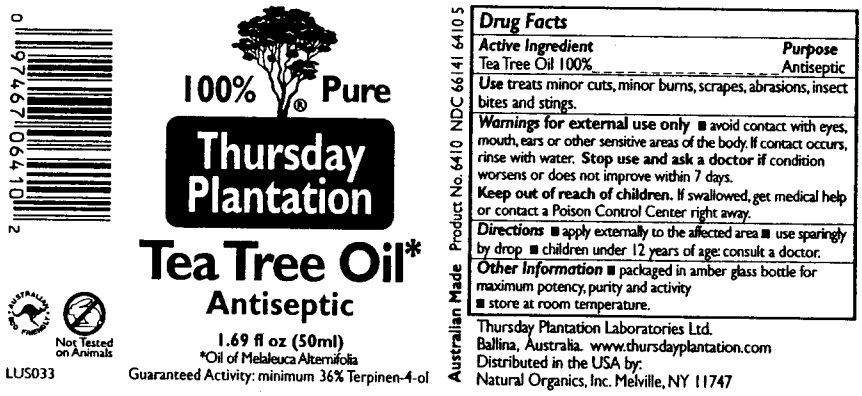
Pacific Highway Ballina NSW 2478 Australia
Telephone: (02) 6686 7273 Facsimile: (02) 6686 7485 International Fax: +61 2 6686 7485

Thursday Plantation
Health from Nature

Thursday Plantation
Laboratories Limited
ABN 17 002 833 141

Schedule 2 to Certificate of a Pharmaceutical

Product No. 02/1022



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