



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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APR 19 2002

Anthony Byrne
General Manager, Research
Rural Industries Research and Development Corporation
Level 1 AMA House
42 Macquarie St
Barton ACT 2600
Australia

75N-183H
Re: Docket No. ~~78N-183H~~
Comment No. CPI

Dear Mr. Byrne:

This letter concerns a citizen petition (CP) dated January 20, 1995, submitted by Martha Smith on behalf of Mitech Laboratories and in collaboration with the American Tea Tree Association (ATTA) and the Australian Tea Tree Industry Association (ATTIA). The petition is filed under Docket No. 78N-183H in the Dockets Management Branch. The petition requests that the agency: 1) Grant a waiver from enforcement action for tea tree oil (oil of melaleuca), 2) review the data contained in the petition, and 3) generally recognize tea tree oil 2 to 10 percent as a safe and effective OTC healthcare antiseptic.

A letter from ATTIA dated March 23, 1995, transferred responsibility for all activities regarding the evaluation of tea tree oil from Mitech Laboratories to C & S Laboratory Consultants Inc. The agency was subsequently informed that C& S Laboratory Consultants Inc. was no longer responsible for coordinating activities concerning the evaluation of tea tree oil. Subsequent submissions on the ingredient have come directly from the ATTA and ATTIA at the above address, with your name on the latest submission.

We have reviewed the information provided in the petition, which includes information on the history of use of tea tree oil as a germicide in various disease states and wounds in Australia. We note that tea tree oil has no marketing history in the United States as a healthcare antiseptic.

The agency has developed a process by which drugs without specific marketing experience in the United States could become eligible for consideration in the agency's over-the-counter (OTC) drug review. We are pleased to inform you that the process is now being implemented.

This process is described in a final rule entitled "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded," which was published in the Federal Register of January 23, 2002 (67 FR

75N-183H

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3060). A copy is enclosed for your information. This final rule is effective on February 22, 2002.

The final rule requires the submission of a Time and Extent Application (TEA) (see § 330.14(c)) to request consideration under the OTC drug review. The required information and format for a TEA are set out in the final rule (see § 330.14(c)). Three copies of the TEA are to be submitted to the Central Document Room (see § 330.14(d)).

If you wish to pursue inclusion in the OTC drug monograph system of an OTC drug product or active ingredient that was the subject of the above CP, please submit a TEA in the required format. We do not intend to take further action on the above CP.

As stated in comment 20 of the final rule that established the TEA process, the agency will give priority to TEA's associated with pending CP's if those CP's are converted to TEA's that are submitted within 120 days after publication of that final rule. We look forward to reviewing your TEA upon submission.

Sincerely yours,



Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

Enclosure